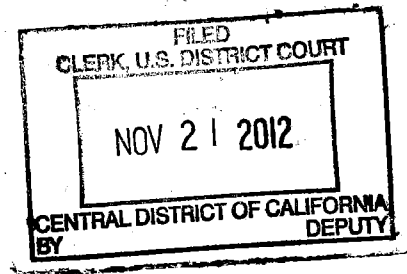


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7 *Pharmaceuticals, Inc.*



8 UNITED STATES DISTRICT COURT
9 CENTRAL DISTRICT OF CALIFORNIA
10

11 MARGALIT CORBER; RENE CARO;
STEVE DANTZLER; LINDA
12 SOWARDS; LORI HUISMAN;
JOHNNY GEORGE SR.; TERRY
13 PERRY; WILLIAM RACKLEY;
ANGELA YOUNG; PAMELA
14 RODRIGUEZ; STEVEN SYVERSON;
OLGA CAICOYA; JANET
15 CARROLL; ROSE CASH; ULAD
CELENTANO; VIRGINIA
16 COSTANZO; KIMBERLY FILLIGIM;
ARMELDIA SMITH; CARLA WEST;
17 JOANNE BIERZYNŃSKI
INDIVIDUALLY AND AS NEXT OF
18 KIN TO ELEANOR WOJCIK;
SHARLEY MORRIS; WYOMIA
19 TIMMONS; DEAN REINKING;
DANIEL THORNE; WENDELEN
20 ASHBY; CARMEN BEDFORD;
CLAUDE COMMODORE; JAMES
21 HENSON; NANCY LOCKE;
MILDRED SCOTT; BILLIE
22 BURNETT; SHEENA HALL;
BRENDA ROBERGE
23 INDIVIDUALLY AND AS NEXT OF
KIN TO ERNEST ROBERGE;
24 DEBORAH WOODSUM; AND
RICHARD PASCUITO.

25 Plaintiffs,

26 v.

27 MCKESSON CORPORATION; ELI
28

CASE NO **CV 12 9986** -G/MK
(RZ)

**NOTICE OF REMOVAL BY
DEFENDANT XANODYNE
PHARMACEUTICALS, INC.
UNDER 28 U.S.C. §§ 1331, 1332,
1367, 1441, 1446, AND 1453**

1 LILLY AND COMPANY;
 2 AAIPHARMA, INC; AAIPHARMA
 3 LLC; AAI DEVELOPMENT
 4 SERVICES, INC.; NEOSAN
 5 PHARMACEUTICALS INC;
 6 XANODYNE PHARMACEUTICALS,
 7 INC; QUALITEST
 8 PHARMACEUTICALS, INC.;
 9 VINTAGE PHARMACEUTICALS,
 10 INC.; PROPST DISTRIBUTION, INC.;
 11 BRENN DISTRIBUTION, INC.;
 12 BRENN MANUFACTURING, INC.;
 13 VINTAGE PHARMACEUTICALS,
 14 LLC; GENERICS INTERNATIONAL
 15 (US), INC.; GENERICS BIDCO I,
 16 LLC; GENERICS BIDCO II, LLC;
 17 GENERICS INTERNATIONAL (US
 18 PARENT), INC.; ENDO
 19 PHARMACEUTICALS, INC.; ENDO
 20 PHARMACEUTICALS HOLDINGS
 21 INC.; CORNERSTONE
 22 BIOPHARMA, INC.;
 23 CORNERSTONE BIOPHARMA
 24 HOLDINGS, INC.; TEVA
 25 BIOPHARMACEUTICALS, INC.;
 26 TEVA PHARMACEUTICALS USA,
 27 INC.; MYLAN
 28 PHARMACEUTICALS, INC.;
 MYLAN, INC.; COVIDIEN PLC;
 COVIDIEN INC.; MALLINCKRODT
 INC.; WATSON
 PHARMACEUTICALS, INC.; ABLE
 LABORATORIES; ARISTOS
 PHARMACEUTICALS, INC.; and
 DOES 1 through 50, inclusive,

Defendants.

Defendant Xanodyne Pharmaceuticals, Inc. ("Xanodyne")¹ hereby removes to
 this Court the state court action described below. Removal is warranted under 28

¹ Xanodyne should be dismissed from this action because it is not subject to
 personal jurisdiction on the claims of any plaintiff who is not a California resident.
Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. ___, 131 S. Ct. 2846,
 180 L. Ed. 2d 796, 2011 U.S. LEXIS 4801 (2011) and *J. McIntyre Machinery, Ltd. v.*
Nicastro, 564 U.S. ___, 131 S. Ct. 2780, 180 L. Ed. 2d 765, 2011 U.S. LEXIS 4800
 (2011) (plurality opinion).) Xanodyne will fully brief its objection to personal
 jurisdiction pursuant to the requirements of Rule 81(c) of the Federal Rules of Civil
 Procedure.

1 U.S.C. §§ 1441(b), 1446, and 1453 because this is a civil action over which this
2 Court has original jurisdiction under 28 U.S.C. §§ 1331, 1332, and 1367. In support
3 of removal, Xanodyne states as follows:

4 **BACKGROUND**

5 1. On or about November 15, 2012, Plaintiffs commenced this action by
6 filing a complaint in the Superior Court of Los Angeles County, in the State of
7 California, bearing case number BC495753. Plaintiffs are 35 individuals who allege
8 cardiovascular injuries as a result of ingestion of prescription pain medications
9 containing the active ingredient propoxyphene. (*See* Ex. A, Compl. ¶ 100.) Plaintiffs
10 improperly fail to allege which form of propoxyphene they took, which Defendant
11 manufactured it, or what cardiovascular injury they allegedly experienced.

12 2. Plaintiffs assert claims against numerous entities they allege are or were
13 involved in the manufacture of brand name and generic prescription pain medications
14 containing propoxyphene (*id.* ¶¶ 27-98) and also against one purported distributor of
15 prescription medications, McKesson Corporation (“McKesson”). (*Id.* ¶¶ 20-26.)
16 Plaintiffs seek to recover compensatory and punitive damages against all Defendants
17 under numerous legal theories, including that the entities allegedly involved in the
18 manufacture of generic prescription medications containing propoxyphene (the
19 “Generic Defendants”) have improperly breached their duty to use the same FDA-
20 approved labeling as the brand companies. (*See id.* ¶¶ 5-7.)

21 3. The instant action is one of more than twenty multi-plaintiff lawsuits
22 alleging injuries from ingestion of propoxyphene-containing pain products filed from
23 approximately November 9, 2012 to November 16, 2012, in numerous California
24 counties. These lawsuits join seven other lawsuits alleging injury resulting from
25 ingestion of propoxyphene pain products filed in Los Angeles and San Francisco
26 Counties in late 2011 and early 2012.

1 4. On October 23, 2012, attorneys from Khorrami, LLP (Oakland CA),
2 Davis & Crump PC (Gulfport MS), The Sill Law Group PLLC (Edmond OK) and
3 Pearson Randall & Schumacher, PA (Minneapolis, MN) ("Coordination Counsel")
4 filed a petition with the California Judicial Counsel to establish a coordinated
5 proceeding before a single trial judge for California state-court products liability
6 actions alleging personal injuries due to prescription pain medications containing
7 propoxyphene. (*See* Ex. B, Pet. for Coord.) In support of the Petition, Coordination
8 Counsel claims that "[o]ne judge hearing all of the actions for all purposes in a
9 selected site or sites will promote the ends of justice." (Ex. C, Mem. in Support of
10 Pet. for Coord. at 8.)

11 5. The Petition for Coordination specifically identifies the seven "original"
12 actions described in paragraph 3 above, which embrace the claims of more than 100
13 individual Plaintiffs, and specifically states that Coordination Counsel intends to
14 include in the coordination additional, then-unfiled claims. (*Id.*) Significantly,
15 subsequent to the filing of the Petition for Coordination, Elise Sanguinetti, whose
16 firm Khorrami LLP serves as Coordination Counsel and who submitted a declaration
17 in support of the Petition for Coordination, has moved to stay the seven original
18 actions pending a ruling on coordination, stating that "[c]oordination of *all* the
19 California Propoxyphene cases makes sense." (*See* Ex. D, Mem. in Supp. of Mot. to
20 Stay at 4, *Freitas v. McKesson Corp.*, No. CGC 11-515537 (Cal. Super. Ct. S.F.
21 County Nov. 9, 2012) (emphasis added).)² Thus, the Petition now embraces the
22 claims of more than 500 individual Plaintiffs.

23

24

25

26 ² Since the Petition for Coordination was filed Xanodyne has become aware of
27 at least 21 additional multi-plaintiff actions filed, not including the above captioned
28 action, alleging injury from the ingestion of propoxyphene containing products
consisting of well over 500 additional plaintiffs. These actions have been identified
in the Notice of Related Actions, filed concurrently herewith.

28

1 6. As set forth more fully below, this case is properly removed to this
2 Court pursuant to 28 U.S.C. § 1441 because there is federal jurisdiction on three
3 independent grounds – (a) as a mass action, pursuant to 28 U.S.C. § 1332(d)(11); and
4 (b) under federal question and supplemental jurisdiction pursuant to 28 U.S.C. §§
5 1331 and 1367– and Xanodyne has satisfied the procedural requirements for removal
6 set forth in 28 U.S.C. §§ 1446 and 1453.

7 **THIS CASE IS REMOVABLE AS A MASS ACTION**

8 7. This case is removable pursuant to the mass action provisions of the
9 diversity jurisdiction statute. 28 U.S.C. § 1332(d)(11). An action is removable as a
10 mass action where it meets the following requirements:

11 a. It involves the monetary relief claims of 100 or more persons that
12 are proposed to be tried jointly on the ground that the plaintiffs' claims involve
13 common questions of law or fact, *see id.* § 1332(d)(11)(B)(i);

14 b. The aggregate amount in controversy exceeds \$5,000,000 and the
15 claims of the individual plaintiffs each exceed the amount of \$75,000, *see id.*
16 §§ 1332(a), (d)(2), (d)(11)(B)(i); and

17 c. Any plaintiff is a citizen of a State different from any defendant,
18 *see id.* § 1332(d)(2)(A).

19 8. As set forth below, this action and the other propoxyphene actions
20 embraced by the Petition for Coordination satisfy all the jurisdictional requirements
21 for a mass action. In addition, Xanodyne has satisfied all procedural requirements for
22 removal of a mass action pursuant to 28 U.S.C. §§ 1446 and 1453. Accordingly,
23 mass action removal is proper.

24 **A. The Petition for Coordination Proposes Joint Trial of the Claims of**
25 **100 or More Persons**

26 9. This action is removable as a mass action because the Petition for
27 Coordination proposes to try this case jointly with numerous other propoxyphene
28

1 actions embracing the claims of more than 500 individuals. (See Pet. for Coord. at 3-
2 7.) As the Seventh Circuit recently held in *In re Abbott Laboratories, Inc.*, No. 12-
3 8020, 2012 WL 4875584 (7th Cir. Oct. 16, 2012) (to be published in F.3d), a petition
4 for state-court coordination of individual actions may render those actions a “mass
5 action” for purposes of removal where, as here, the coordination petition proposes
6 joint trial of the individual actions. *See id.* at *1. And while a mass action does not
7 result where individual actions are joined “upon motion of a defendant,” 28 U.S.C. §
8 1332(d)(11)(B)(ii)(II); *see also Tanoh v. Dow Chemical Co.*, 561 F.3d 945, 953 (9th
9 Cir. 2009); *Anderson v. Bayer Corp.*, 610 F.3d 390, 393 (7th Cir. 2010), there is no
10 such barrier where, also as here, the proposal for joint trial originates with the
11 plaintiffs. *See Abbott*, 2012 WL 4875584, at *3.

12 10. Here, the proposal for joint trial in the Petition for Coordination is even
13 clearer than it was in *Abbott*. In that case, the Seventh Circuit held that a petition for
14 coordination need not specifically request joint trial because “a proposal for a joint
15 trial can be implicit.” *Id.* at *3; *see also Bullard v. Burlington N. Santa Fe Ry. Co.*,
16 535 F.3d 759, 762 (7th Cir. 2008); *Koral v. Boeing Co.*, 628 F.3d 945, 947 (7th Cir.
17 2011). The Seventh Circuit found that the plaintiffs’ coordination petition implicitly
18 requested a joint trial where it sought coordination “‘through trial’” and “‘not solely
19 for pretrial proceedings’” and asserted that coordination “‘through trial ‘would also
20 facilitate the efficient disposition of a number of universal and fundamental
21 substantive questions applicable to all or most Plaintiffs’ cases *without the risk of*
22 *inconsistent adjudication* in those issues between various courts.’” *Abbott*, 2012 WL
23 4875584, at *3 (citation omitted).

24 11. Here, the Petition for Coordination presents all of the factors (and more)
25 that the Seventh Circuit held constituted a request for a joint trial in *Abbott*. Initially,
26 like the *Abbott* plaintiffs’ request for coordination “‘through trial,” the Petition here
27 proposes “[o]ne judge hearing *all of the actions* for *all purposes* in a selected site or
28

1 sites” in order to “promote the ends of justice.” (Mem. in Supp. of Pet. for
2 Coordination at 8 (emphasis added).) Coordination for “all purposes” naturally
3 embraces coordination for trial.

4 12. Moreover, like the *Abbott* plaintiffs’ assertions concerning the “*risk of*
5 *inconsistent adjudication*,” the Petition for Coordination here emphasizes that
6 “[f]ailure to coordinate these actions will result in the disadvantages of duplicate and
7 inconsistent rulings, orders, or judgments” as to “issues pertaining to liability,
8 allocation of fault and contribution, as well as the same wrongful conduct of
9 defendants.” (Mem. in Supp. of Pet. for Coordination at 10; *see also id.* at 6, 8; Ex.
10 E, Sanguinetti Decl. in Supp. of Coordination ¶ 11 (“Without coordination, two or
11 more separate courts will decide essentially the same issues and may render different
12 rulings on liability and other issues.”).) In the same vein, the Petition for
13 Coordination here argues that there are “common issues” among each of the
14 constituent actions, including *whether the plaintiffs are entitled to compensatory and*
15 *punitive damages*. (See Sanguinetti Decl. in Supp. of Coordination ¶ 7.) The
16 Petition’s proposal to resolve the determinations of liability, allocation of fault, and
17 award of compensatory and punitive damages as “common issues” necessarily
18 requires a joint trial.³

19 13. Indeed, the Seventh Circuit cited similar remarks by plaintiffs
20 concerning the risk of inconsistent adjudication of purported common issues when it
21 observed that “it is difficult to see how a trial court could consolidate the cases as
22 requested by plaintiffs and not hold a joint trial or an exemplar trial with the legal
23 issues applied to the remaining cases. In either situation, plaintiffs’ claims would be
24 tried jointly.” *Abbott*, 2012 WL 4875584, at *3; *see also* 28 U.S.C. §

25
26 ³ Xanodyne does not concede that Plaintiffs are entitled to a joint trial, but
27 merely notes that the Petition for Coordination proposes one, thereby entitling
28 Defendants to remove the cases pursuant to the mass action provisions of 28 U.S.C. §
1332.

1 1332(d)(11)(B)(i) (providing that the mass action standard is satisfied where joint
2 trial is proposed “on the ground that the plaintiffs’ claims involve common questions
3 of law or fact”). Thus, even a joint trial as to certain issues, which the Petition for
4 Coordination repeatedly suggests in its discussion of avoiding inconsistent rulings as
5 to “common issues,” is sufficient to establish mass action jurisdiction pursuant to 28
6 U.S.C. § 1332(d)(11).

7 14. In addition, the Petition for Coordination envisions that a joint trial
8 would put pressure on Defendants to settle all California propoxyphene cases.
9 Coordination Counsel’s declaration in support of the Petition states that one of the
10 primary motivating factors for settling cases is “the avoidance of the risk of an
11 adverse judgment at trial.” (Sanguinetti Decl. in Supp. of Coordination ¶ 12.)
12 Coordination Counsel argues that coordination is mandated here because if the cases
13 are not coordinated, “[s]ettlement of one of these cases may not end the litigation in
14 the other . . . cases.” (*Id.*) Implicit in this call for settlement is a proposal for joint
15 trial: in order for the threat of adverse judgment at trial to compel settlement or end
16 litigation in the other cases, there must be either a joint trial of all cases, or a
17 judgment at an exemplar trial that is binding on the other cases. Thus, “[i]n either
18 situation” there is a proposal for joint trial and the first mass action requirement is
19 satisfied. *Abbott*, 2012 WL 4875584, at *3.

20 15. Finally, as in *Abbott*, Plaintiffs have done nothing to suggest that they
21 propose coordination “solely for pretrial proceedings.” 28 U.S.C. §
22 1332(d)(11)(B)(ii)(IV); *see also Abbott*, 2012 WL 4875584, at *3. To the contrary,
23 for all the reasons set forth above, the Petition for Coordination necessarily
24 constitutes a proposal for coordination for trial.

25 16. Accordingly, the Petition for Coordination proposes joint trial of the
26 monetary claims of more than 100 individuals, and the first requirement of mass
27 action removal is satisfied.

28

B. The Amount in Controversy Is Satisfied

17. Both the individual \$75,000 and aggregate \$5,000,000 amount in controversy requirements for mass action removal are readily satisfied. *See* 28 U.S.C. §§ 1332(a), (d)(2), (d)(11)(B)(i). Indeed, the Petition for Coordination itself admits that there are “multi-millions of dollars at stake” in these cases (Pet. for Coord. at 10), and Coordination Counsel has publicly stated that the propoxyphene litigation “has the potential to be in the billions of dollars for recoveries around the country.”⁴

18. First, it is apparent from the face of the Complaint, and the serious nature of the “severe cardiovascular injuries” alleged by each Plaintiff (*see* Compl. ¶ 100), that the amount in controversy exceeds \$75,000 for each Plaintiff, just as it is for the claims in the other actions embraced by the Petition. Where, as here, Plaintiffs allege serious bodily injuries, courts have readily found that the amount-in-controversy requirement is satisfied. *See In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 296 (S.D.N.Y. 2001). In addition, compensatory and punitive damages in excess of the jurisdictional amount of \$75,000 have been awarded in products liability cases in California. *See, e.g., Stewart v. Union Carbide Corp.*, 190 Cal. App. 4th 23, 38, 117 Cal. Rptr. 3d 791, 804 (2010); *Karlsson v. Ford Motor Co.*, 140 Cal. App. 4th 1202, 1223-24, 45 Cal. Rptr. 3d 265, 282-83 (2006); *Jones v. John Crane, Inc.*, 132 Cal. App. 4th 990, 1012, 35 Cal. Rptr. 3d 144, 161 (2005). Other federal courts have thus concluded that the amount in controversy exceeded \$75,000 in similar pharmaceutical cases. *See, e.g., Smith v. Wyeth, Inc.*, 488 F. Supp. 2d 625, 630-31 (W.D. Ky. 2007) (denying motion to remand); *accord Copley v. Wyeth, Inc.*, No. 09-722, 2009 WL 1089663, at *3 (E.D. Pa. Apr. 22, 2009). In addition, because

⁴ Olivia Whitaker, *Oklahoma Attorney Predicts Billions of Dollars in Darvocet Lawsuit Recoveries* (Feb. 9, 2011), available at <http://www.articlesbase.com/mental-health-articles/oklahoma-attorney-predicts-billions-of-dollars-in-darvocet-lawsuit-recoveries-4199525.html>.

1 Plaintiffs' demands for punitive damages are also includable in the amount in
 2 controversy, *see Guglielmino v. McKee Foods Corp.*, 506 F.3d 696, 700 (9th Cir.
 3 2007), it is evident, from the face of the Complaint, that the amount of recovery
 4 sought by each Plaintiff exceeds \$75,000.⁵

5 19. Second, because each individual Plaintiff's claim exceeds \$75,000, the
 6 aggregate amount in controversy for putative coordinated litigation, which embraces
 7 the claims of more than 500 individuals, necessarily exceeds \$5,000,000, since
 8 \$75,000 multiplied by 500 is \$37,500,000.

9 20. Accordingly, the amount-in-controversy requirement is satisfied.

10 C. The Diversity Requirement Is Satisfied

11 21. The diversity requirements for mass action removal have been satisfied.
 12 *See* 28 U.S.C. § 1332(d)(2)(A). While diversity removal normally requires complete
 13 diversity between plaintiffs and defendants, for removal of a mass action, only
 14 "minimal diversity" is required – i.e., that at least one plaintiff be diverse from one
 15 defendant. *See id.* This requirement is readily satisfied here: Plaintiff Margalit
 16 Corber, a citizen of California (Compl. ¶ 101), is diverse from Lilly, a citizen of
 17 Indiana. (*Id.* ¶ 27.)

18 22. Accordingly, all the jurisdictional requirements of mass action removal
 19 are satisfied.

20 **THIS CASE IS REMOVABLE UNDER FEDERAL QUESTION AND** 21 **SUPPLEMENTAL JURISDICTION**

22 23. This action is removable under the CAFA "mass action" provisions
 23 alone. However, as a separate and independent basis for removal, this action is also

24 ⁵ Xanodyne notes that it is not required to concede that Plaintiffs are, in fact,
 25 entitled to recover more than \$75,000. *See Kelderman v. Remington Arms Co.*, 734
 26 F. Supp. 1527, 1528 (S.D. Iowa 1990) (rejecting a plaintiff's attempt to "place [a]
 27 defendant in the awkward position of embracing a concession on the important issue
 28 of damages," to establish jurisdiction, noting that a "defendant need not go that far").
 Indeed, Xanodyne specifically denies that Plaintiffs are entitled to recover any
 damages.

properly removable under 28 U.S.C. §§ 1331 and 1367. Plaintiffs' claims against Generic Defendants are removable because they necessarily raise a substantial and disputed question of federal law. In addition, all remaining claims are removable subject to the Court's supplemental jurisdiction.

A. Plaintiffs' Claims Against Generic Defendants Are Removable Because They Necessarily Raise Substantial Issues of Federal Law

24. Plaintiffs' claims against Generic Defendants are removable because they necessarily raise a substantial and disputed question of federal law. The Supreme Court has held that state-law claims are removable under federal question jurisdiction pursuant to 28 U.S.C. § 1331 where they "necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005).

25. Federal jurisdiction exists where a state law claim necessarily involves the construction or application of federal law. *See, e.g., D'Alessio v. New York Stock Exchange, Inc.*, 258 F.3d 93, 99 (2d Cir. 2001) ("[A] case is deemed 'to arise under' federal law 'where the vindication of a right under state law necessarily turn[s] on some construction of federal law.'" (alteration in original) (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9 (1983))).

26. In addition, this Court has original and removal jurisdiction of civil actions, such as this one, that arise "under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331, 1441(a). Among the civil actions that "arise under" federal law are "state-law claims that implicate significant federal issues." *Grable*, 545 U.S. at 312. Such claims capture the "commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the

1 experience, solicitude, and hope of uniformity that a federal forum offers on federal
2 issues.” *Id.*

3 27. Thus, federal question jurisdiction also exists where, as here, a “state
4 law claim necessarily raise[s] a stated federal issue, actually disputed and substantial,
5 which a federal forum may entertain without disturbing any congressionally approved
6 balance of federal and state judicial responsibilities.” *Id.* at 314.

7 28. The claims asserted in Plaintiffs’ Complaint meet both of these
8 standards for federal question jurisdiction. As the Eastern District of New York has
9 recently held, claims against generic defendants are removable under *Grable* where,
10 like Plaintiffs’ claims here, they allege that the generic defendants are liable in
11 failure-to-warn due to breach of their federal duty to use the same FDA-approved
12 labeling as the brand defendants. *Bowdrie v. Sun Pharm. Indus. Ltd.*, No. 12-CV-853
13 (WFK) (MDG), 2012 WL 5465994 (E.D.N.Y. Nov. 9, 2012).

14 29. As recognized by the Supreme Court in *PLIVA, Inc. v. Mensing*, 131 S.
15 Ct. 2567 (2011), generic defendants are prohibited by federal law from independently
16 changing the labeling for their products, but are instead required by federal law to use
17 labeling identical to the FDA-approved labeling used by the brand defendant. *See id.*
18 at 2578. The plaintiffs in *Bowdrie* alleged that the generic defendants were liable on
19 state-law failure-to-warn claims because they breached their duty to employ the same
20 labeling as the brand defendants. 2012 WL 5465994, at *1.

21 30. The *Bowdrie* court held that the plaintiffs’ state-law claims that generic
22 defendants “failed to meet their ongoing duty of sameness by failing to . . . update
23 their FDA-approved labeling to mirror updated [brand drug] labeling . . . necessarily
24 raise[d] a federal question.” 2012 WL 5465994, at *3 (“A question of federal law is
25 a necessary element of Plaintiffs’ state law causes of action.”). The court further held
26 that this federal question was substantial because it:

1 goes far beyond simply incorporating a federal standard into a
2 state law cause of action. To the extent they invoke the “federal
3 duty of sameness,” Plaintiffs’ causes of action implicate the
4 labeling requirements for generic drug manufacturers nationwide.
5 The federal question present in this case involves a responsibility
6 that is in the first instance, and primarily, federal: regulation of
7 the manufacture, marketing, and distribution of drugs.

8 *Id.* at *4. Thus, the court held, the Plaintiffs’ claims were removable under federal
9 question jurisdiction under the rule of *Grable*. *Id.* at *3.

10 31. The same reasoning applies to this action, where, just like in *Bowdrie*,
11 Plaintiffs claim that Generic Defendants are liable in failure-to-warn due to their
12 alleged failure to update their labeling to conform to the brand. (See Compl. ¶¶ 6-7.)

13 32. It is irrelevant that Plaintiffs may not have intended to plead a state law
14 cause of action that raises a substantial and disputed issue of federal law to establish a
15 basis for jurisdiction arising from a federal question. In *Grable*, the Supreme Court
16 held that federal question jurisdiction exists when a state law cause of action raises a
17 substantial federal question that is in dispute. *Grable*, 545 U.S. at 316-20. Plaintiffs
18 may not avoid this result through artful pleading. See *Rivet v. Regions Bank*, 522
19 U.S. 470, 475 (1998) (holding that “[i]f a court concludes that plaintiff has ‘artfully
20 pleaded’ claims” by omitting to plead federal questions, “it may uphold removal even
21 though no federal question appears on the face of the plaintiff’s complaint”).

22 33. Accordingly, Plaintiffs’ failure-to-update claims against Generic
23 Defendants are properly removable under federal question jurisdiction pursuant to the
24 rule of *Grable* because they necessarily (indeed, affirmatively) raise a substantial,
25 disputed issue of federal law.

26 **B. Supplemental Jurisdiction Extends to All Other Claims**

27 34. This Court has “supplemental jurisdiction over all other claims that are
28 so related to claims in the action within [the Court’s] original jurisdiction that they
form part of the same case or controversy under Article III of the United States

1 Constitution.” 28 U.S.C. § 1367(a). As set forth above, Plaintiffs’ claims against
2 Generic Defendants are within the Court’s original jurisdiction pursuant to 28 U.S.C.
3 § 1331. On an individual, per-Plaintiff basis, all other claims in this action arise out
4 of the same case or controversy in that they seek relief in connection with personal
5 injuries allegedly due to the ingestion of a propoxyphene-containing pain medication.

6 35. Accordingly, there is supplemental jurisdiction over all other claims in
7 this action.

8 **ALL REMOVAL PROCEDURES ARE SATISFIED**

9 36. Because this case is removable as a mass action together with the other
10 actions embraced by the Petition for Coordination, all of those cases are being
11 removed upon substantially the same grounds.

12 37. Xanodyne has not yet been served in this action. Accordingly, this
13 removal is timely, since Xanodyne was not required to remove until 30 days from
14 service of the Complaint. *See* 28 U.S.C. § 1446(b)(1).

15 38. All defendants properly joined and served consent to the removal of this
16 action, since Xanodyne is informed that only McKesson has been served in this
17 action and that McKesson consents to its removal. *See id.* § 1446(b)(2)(A). In
18 addition, Xanodyne states that, with respect to the mass action removal, the consent
19 of other Defendants to remove is not required. *See id.* § 1453(b).

20 39. Removal is not barred by the California citizenship of any Defendant.
21 *See id.* §§ 1441(a), 1453(b).

22 40. As Xanodyne has not been served in this action, no pleadings and
23 process have been served on the removing defendant. *See id.* § 1446(d).

24 41. Written notice of this removal is being provided to all adverse parties
25 and is being filed with the clerk of the California Superior Court. *See id.*

26 42. Xanodyne hereby reserves the right to amend this notice of removal.
27
28

1 WHEREFORE, Xanodyne respectfully removes this action from the Superior
2 Court of the County of Log Angeles, in the State of California, bearing Number
3 BC495753, to this Court.

4 DATED: November 20, 2012

Respectfully submitted,

5
6 SEDGWICK LLP

7 By: 

8 Karen Woodward
9 Christopher P. Norton
Attorneys for Defendant
Xanodyne Pharmaceuticals, Inc.

EXHIBIT A

ORIGINAL

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NOV 15 2012

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IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
 IN AND FOR THE COUNTY OF LOS ANGELES

MARGALIT CORBER; RENE CARO; STEVE
 DANTZLER; LINDA SOWARDS; LORI
 HUISMAN; JOHNNY GEORGE SR.; TERRY
 PERRY; WILLIAM RACKLEY; ANGELA
 YOUNG; PAMELA RODRIGUEZ; STEVEN
 SYVERSON; OLGA CAICOYA; JANET
 CARROLL; ROSE CASH; ULAD CELENTANO;
 VIRGINIA COSTANZO; KIMBERLY FILLIGIM;
 ARMELDIA SMITH; CARLA WEST; JOANNE
 BIERZYNSKI INDIVIDUALLY AND AS NEXT
 OF KIN TO ELEANOR WOJCK; SHARLEY
 MORRIS; WYOMIA TIMMONS; DEAN
 REINKING; DANIEL THORNE; WENDELEN
 ASHBY; CARMEN BEDFORD; CLAUDE
 COMMODORE; JAMES HENSON; NANCY
 LOCKE; MILDRED SCOTT; BILLIE BURNETT;
 SHEENA HALL; BRENDA ROBERGE
 INDIVIDUALLY AND AS NEXT OF KIN TO

CASE NO.: **BC495753**
COMPLAINT FOR DAMAGES
DEMAND FOR JURY TRIAL

Causes of Action:
 (As to All Defendants)
 1. Strict Products Liability
 Defect
 2. Strict Products Liability
 Warn
 3. Strict Liability in Tort
 4. Negligent Design
 5. Negligence
 6. Negligent Failure to Warn
 7. Fraudulent Non-Disclosure
 8. Negligent Misrepresentation

CIT/CASE: BC495753
 LEA/DEF#:
 RECEIPT #: CCH465980048
 DATE PAID: 11/15/12 11:45 AM
 PAYMENT: \$1,000.00
 RECEIVED:
 CHECK: \$1,000.00
 CASH: \$0.00
 CHANGE: \$0.00
 CARD: \$0.00

\$1,000.00
 \$0.00
 \$0.00
 \$0.00

CIT/CASE: BC495753
 LEA/DEF#:
 RECEIPT #: CCH465980047
 DATE PAID: 11/15/12 11:44 AM
 PAYMENT: \$435.00
 RECEIVED:
 CHECK: \$435.00
 CASH: \$0.00
 CHANGE: \$0.00
 CARD: \$0.00

28 for the Palmyra

28 for the Palmyra

1 ERNEST ROBERGE; DEBORAH WOODSUM;
2 AND RICHARD PASCUITO.

3 Plaintiffs,

4 vs.

5 MCKESSON CORPORATION; ELI LILLY AND
6 COMPANY; AAI PHARMA, INC; AAI PHARMA
7 LLC; AAI DEVELOPMENT SERVICES, INC.;
8 NEOSAN PHARMACEUTICALS INC;
9 XANODYNE PHARMACEUTICALS, INC.;
10 QUALITEST PHARMACEUTICALS, INC.;
11 VINTAGE PHARMACEUTICALS, INC.;
12 PROPST DISTRIBUTION, INC.; BRENN
13 DISTRIBUTION, INC.; BRENN
14 MANUFACTURING, INC.; VINTAGE
15 PHARMACEUTICALS, LLC;
16 GENERICS INTERNATIONAL (US), INC.;
17 GENERICS BIDCO I, LLC; GENERICS BIDCO
18 II, LLC; GENERICS INTERNATIONAL (US
19 PARENT), INC.; ENDO PHARMACEUTICALS,
20 INC.; ENDO PHARMACEUTICALS HOLDINGS
21 INC.; CORNERSTONE BIOPHARMA, INC.;
22 CORNERSTONE BIOPHARMA HOLDINGS,
23 INC.; TEVA BIOPHARMACEUTICALS, INC.;
24 TEVA PHARMACEUTICALS USA, INC.;
25 MYLAN PHARMACEUTICALS, INC.; MYLAN,
26 INC.; COVIDIEN PLC; COVIDIEN INC.;
27 MALLINCKRODT INC.; WATSON
28 PHARMACEUTICALS, INC.; ABLE
LABORATORIES; ARISTOS
PHARMACEUTICALS, INC.; and DOES 1
through 50, inclusive,

Defendants.

) 9. Fraudulent Misrepresentation and
) Concealment
) 10. Negligence Per Se
) 11. Breach of Express Warranty
) 12. Breach of Implied Warranty
) 13. Deceit by Concealment – Violation
) of California Civil Code §§ 1709, 1710
) 14. Violation of Business and
) Professions Code § 17200
) 15. Violation of Business and
) Professions Code § 17500
) 16. Violation of Civil Code § 1750, et
) seq.
) (As to Innovator and Brand
) Defendants)
) 17. Negligence
) 18. Fraudulent Non-Disclosure
) 19. Negligent Misrepresentation
) 20. Fraudulent Misrepresentation and
) Concealment
) (As to All Defendants)
) 21. STRICT LIABILITY: STATE OF
) ALABAMA Code of Alabama §§ 6-5-
) 500 through 6-5-504 and 6-5-520
) through 6-5-525
) 22. STRICT LIABILITY: STATE OF
) ARKANSAS Ark. Code Ann. § 16-116-
) 102
) 23. STRICT LIABILITY: STATE OF
) COLORADO C.R.S.A. § 13-21-401 to
) § 13-21-406 and Restatement (Second)
) Torts, Section 402A
) 24. STRICT LIABILITY: STATE OF
) FLORIDA Restatement (Second)
) Torts, Section 402A
) 25. LIABILITY: STATE OF
) GEORGIA § 51-1-11 OF THE
) GEORGIA CODE
) 26. STRICT LIABILITY: STATE OF
) ILLINOIS Restatement (Second)
) Torts, Section 402A
) 27. STRICT LIABILITY: STATE OF
) INDIANA CLAIMS UNDER THE
) IPLA: Ind. Code. Ann. §24-20 et seq.
) 28. LIABILITY: STATE OF
) KANSAS K.S.A. § 60-3302 et seq.
) 29. STRICT LIABILITY: STATE OF
) MAINE Strict Liability Pursuant to
) Me. Rev. Stat. Ann. tit 14, § 221 (2008)

-) 30. VIOLATION OF CONSUMER
-) PROTECTION ACTS AND
-) DECEPTIVE TRADE PRACTICES
-) ACTS
-) 31. PUNITIVE DAMAGES
-) 32. Wrongful Death
-) 33. Survivorship

INTRODUCTION

1. This lawsuit concerns personal injury and wrongful death related to Plaintiffs' and Decedent's ingestion of prescription medication containing the active ingredient propoxyphene for treatment of mild to moderate pain, marketed and sold as generic and/or brand-name drugs under various names. All such medications that contain propoxyphene, in their various generic and brand-name forms, are referred to in this Complaint as "Propoxyphene Products".

2. Plaintiffs allege that Defendants MCKESSON CORPORATION; ELI LILLY AND COMPANY; AAIPHARMA, INC.; AAIPHARMA LLC; AAI DEVELOPMENT SERVICES, INC.; NEOSAN PHARMACEUTICALS INC.; XANODYNE PHARMACEUTICALS, INC.; QUALITEST PHARMACEUTICALS, INC.; VINTAGE PHARMACEUTICALS, INC.; PROPST DISTRIBUTION, INC.; BRENN DISTRIBUTION, INC.; BRENN MANUFACTURING, INC.; VINTAGE PHARMACEUTICALS, LLC; GENERICS INTERNATIONAL (US), INC.; GENERICS BIDCO I, LLC; GENERICS BIDCO II, LLC; GENERICS INTERNATIONAL (US PARENT), INC.; ENDO PHARMACEUTICALS, INC.; ENDO PHARMACEUTICALS HOLDINGS INC.; CORNERSTONE BIOPHARMA, INC.; CORNERSTONE BIOPHARMA HOLDINGS, INC.; TEVA BIOPHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; MYLAN PHARMACEUTICALS, INC.; MYLAN, INC.; COVIDIEN PLC; COVIDIEN INC.; MALLINCKRODT INC.; WATSON PHARMACEUTICALS, INC.; ABLE LABORATORIES, INC.; ARISTOS PHARMACEUTICALS, INC., and DOES 1 through 50, inclusive, inclusive knowingly or negligently manufactured, marketed, distributed, and sold defectively designed Propoxyphene Products without adequate warnings.

1 3. In July, 2009, the FDA ordered Defendant Xanodyne Pharmaceuticals, Inc.,
2 (hereinafter "Xanodyne") to make changes to the labels of its Propoxyphene Products. These
3 changes included: (a) an addition to the Clinical Pharmacology section of the label discussing the
4 cardiac effects of propoxyphene; (b) a revised boxed warning concerning the risks of both intentional
5 and accidental overdose; (c) the reiteration of this warning regarding the risk of overdose in the
6 Warnings section of the label; and (d) the addition of bolded warnings in the Dosage and
7 Administration section of the label warning against exceeding the maximum daily dose.

8 4. Without further discovery, it is unclear to Plaintiffs whether Xanodyne implemented
9 these required actions during the time that Propoxyphene Products remained on the market.

10 5. By ordering the RLD holder to make these changes to its label, the FDA empowered
11 Generic Manufacturer Defendants to make the same changes to their own product labels through the
12 "Changes Being Effected" (CBE) process that does not require prior FDA approval. 21 C.F.R.
13 §314.70(c). This is true whether or not Xanodyne ever implemented the labeling change.

14 6. The Generic Defendants could have made these labeling changes without running
15 afoul of the requirement of "sameness" because federal law expressly permits generic labeling to
16 differ from RLD labeling where the labeling revision is "made to comply with current FDA labeling
17 guidelines or other guidance." 21 C.F.R. §314.94(a)(8)(iv).

18 7. While Plaintiffs cannot know for certain without further discovery, it appears that
19 certain Generic Defendants never implemented these FDA-approved labeling changes between the
20 time that the FDA ordered the changes in July 2009 and the time that they withdrew Propoxyphene
21 Products from the market. Many of the Plaintiffs used and were injured by Propoxyphene Products
22 during this period and allege that their physicians would not have prescribed Propoxyphene Products
23 to them if they had been informed of these new warnings.

24 8. On information and belief, Defendant McKesson distributed Propoxyphene Products
25 with outdated and inaccurate labeling after July 2009, specifically, (a) an addition to the Clinical
26 Pharmacology section of the label discussing the cardiac effects of propoxyphene; (b) a revised
27 boxed warning concerning the risks of both intentional and accidental overdose; (c) the reiteration of
28 this warning regarding the risk of overdose in the Warnings section of the label; and (d) the addition

1 of bolded warnings in the Dosage and Administration section of the label warning against exceeding
2 the maximum daily dose.

3 9. On information and belief, Defendant McKesson, which distributes more
4 Propoxyphene Products throughout the United States than any other entity, is directly responsible for
5 distributing the Propoxyphene Products with outdated and inaccurate labeling ingested by multiple
6 Plaintiffs in this action.

7 10. Defendants knew or should have known that Propoxyphene Products were ineffective,
8 or at best, marginally effective, and that any benefits of propoxyphene were outweighed by its risks,
9 including serious risks of adverse cardiovascular events that could result in death, as well as other
10 injuries.

11 11. The serious health risks associated with Propoxyphene Products and the many safer
12 alternatives that were available led the British government to declare in a 2005 recall that it could not
13 identify *any* group of patients for whom the benefits of propoxyphene outweighed its risks.

14 12. In turn, in November 2010, the limited utility and significant risks associated with
15 Propoxyphene Products led the United States Food and Drug Administration ("FDA") to take action
16 to get all such products withdrawn from the market, and to get physicians to stop prescribing
17 Propoxyphene Products, but the FDA's actions came too late to prevent Plaintiffs' injuries.

18 13. All Defendants involved in the manufacture, marketing, distribution and sale of those
19 defectively designed drugs must be held liable for those injuries.

20 **PARTIES AND JURISDICTION**

21 14. Plaintiffs allege an amount in controversy in excess of the minimal jurisdictional
22 limits of this Court. A substantial part of the events giving rise to this claim occurred within the
23 County of Los Angeles, State of California. For example, Plaintiff Margalit Corber, a citizen and
24 resident of Los Angeles County, was prescribed Darvocet and suffered injuries as a result, within Los
25 Angeles County.

26 15. The true names or capacities, whether individual, corporate, or otherwise, of
27 Defendants DOES 1 through 50, inclusive, are unknown to Plaintiffs despite Plaintiffs' reasonable
28 attempts to identify Defendant DOES 1 through 50, who therefore sue said Defendants by such

1 fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein by
 2 fictitious names is in some manner legally responsible for the events and happenings herein referred
 3 to and caused damages proximately and foreseeably to Plaintiffs as alleged herein.

4 16. At all times herein alleged, unless specified otherwise, "Defendants" include all herein
 5 named Defendants as well as Defendants DOES 1 through 50, inclusive.

6 17. DOES 1 through 50, and each of them, acted independently of, or jointly with, other
 7 Defendants, and are in some manner legally responsible for the events and happenings herein referred
 8 to, and caused damages proximately and foreseeably to Plaintiffs as alleged herein.

9 18. "Plaintiff" and "Plaintiffs": As used through-out this Complaint, the singular
 10 version of "plaintiff" is also intended to include the plural version of all "plaintiffs" for whom that
 11 section or cause of action applies to. Likewise, the plural version of "plaintiffs" is also intended to
 12 include each individual "plaintiff."

13 19. "Defendant" and "Defendants": As used through-out this Complaint, the singular
 14 version of "defendant" is also intended to include the plural version of all "defendants" for whom that
 15 section or cause of action applies to. Likewise, the plural version of "defendants" is also intended to
 16 include each individual "defendant."

17 DISTRIBUTOR DEFENDANTS

18 20. Defendant MCKESSON CORPORATION (hereinafter, "McKesson"), at all times
 19 alleged herein, is and was a corporation organized and existing under the laws of the State of
 20 Delaware, with its principal place of business in the city of San Francisco, County of San Francisco,
 21 California, duly authorized to transact business in the State of California. At all times alleged herein,
 22 McKesson is and was engaged in the business of marketing, distributing, promoting, advertising and
 23 selling Propoxyphene Products nationwide and specifically within the State of California, including
 24 Los Angeles County, where Plaintiff Margalit Corber and other Plaintiffs resided and/or ingested
 25 Propoxyphene Products.

26 21. On information and belief, McKesson has been integrally involved in marketing,
 27 promoting, distributing, advertising, and merchandising propoxyphene products, including
 28

1 propoxyphene with inaccurate and outdated labeling, nationally, and specifically in the State of
2 California.

3 22. Upon information and belief and subject to discovery of information within the
4 exclusive control of Defendants, McKesson distributed the Propoxyphene Products ingested by
5 multiple Plaintiffs alleged herein to have ingested Propoxyphene Products. McKesson, maintains
6 comprehensive distribution agreements with major retail pharmacies including, but not limited to,
7 CVS, Wal-Mart, and Rite Aid.

8 23. The Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman
9 Amendments"), which amended the federal Food, Drug, and Cosmetic Act, does not address
10 distributor liability.

11 24. McKesson is not only one of the major national distributors of prescription drugs, it is
12 also involved in several levels of marketing, advertising, and promoting products for its drug
13 manufacturing clients.

14 25. On its website, McKesson announces that it delivers to pharmaceutical drug
15 companies, "an unmatched combination of communication, promotion, distribution, and packaging
16 options, plus targeted analytics of exclusive data. McKesson Manufacturing Marketing enables
17 brands to set strategies that prioritize opportunities, optimize resources, and maximize profitability."
18 McKesson further advertises in its National Consumer Outreach Campaigns, to:

19
20 [o]ffer bother pharmacists and manufacturers a high-profile public platform to increase
21 awareness about a variety of health concerns, from general wellness to guidance on
22 complying with specific therapies. McKesson works with manufacturers to tailor
23 campaigns to their specific goals, and enhances the partnership between manufacturers
24 and pharmacists to enhance the success of national consumer outreach campaigns.

25 Moreover, according to its website, McKesson builds "patient awareness through retail
26 merchandising, promotions, and advertising," it increases "patient acquisition by fostering new trial
27 usage," an enhances "pharmacists' brand awareness through multiple communication platforms,
28 online ordering, and in-store promotions." McKesson advertises to pharmaceutical manufacturers,
including those manufacturing propoxyphene, promising not only to deliver drugs, but once there,

1 [y]ou need help promoting your products, getting them on the right shelves, reducing out-
 2 of-stocks, and increasing your sales. Working with McKesson, we empower you to reach
 3 regional and independent pharmacies nationwide. And by supporting you with
 merchandising, front-end promotions, and other strategic programs, we help you grow
 your profits.

4 26. At all times alleged herein, McKesson includes any and all parents, subsidiaries,
 5 affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their
 6 predecessors, successors and assigns and their offices, directors, employees, agents, representatives
 7 and any and all other persons acting on their behalf.

8 INNOVATOR AND BRAND DEFENDANTS

9 27. Defendant Eli Lilly and Company ("Eli Lilly") was at all relevant times a corporation
 10 organized under the laws of Indiana, with its principal place of business located at Lilly Corporate
 11 Center, Indianapolis, Indiana 46285.

12 28. Defendant, aaiPharma, Inc., ("aaiPharma") was at all relevant times a corporation
 13 organized under the laws of Delaware, with its principal place of business located at 2320 Scientific
 14 Park Drive, Wilmington, North Carolina 28405.

15 29. Defendant aaiPharma LLC ("aaiPharma LLC") was at all relevant times a limited
 16 liability company organized under the laws of Delaware, with its principal place of business located
 17 at 2320 Scientific Park Drive, Wilmington, North Carolina 28405.

18 30. Defendant AAI Development Services, Inc. ("AAI DS") was at all relevant times a
 19 corporation organized under the laws of Delaware, with its principal place of business located at 2320
 20 Scientific Park Drive, Wilmington, North Carolina 28405. AAI DS was at all relevant times a
 21 division of aaiPharma.

22 31. Defendant NeoSan Pharmaceuticals Inc. ("NeoSan") was at all relevant times a
 23 corporation organized under the laws of Delaware, with its principal place of business located at 2320
 24 Scientific Park Drive, Wilmington, North Carolina 28405. NeoSan was at all relevant times a
 25 commercialization business unit of aaiPharma.

26 32. Defendant's aaiPharma, aaiPharma LLC, AAI DS, and NeoSan shall be referred to
 27 herein individually by name or jointly as the "aaiPharma Entities."
 28

1 33. Defendant Xanodyne Pharmaceuticals, Inc. ("Xanodyne") was at all relevant times a
2 corporation organized under the laws of Delaware, with its principal place of business located at One
3 Riverfront Place, Newport, Kentucky 41071.

4 34. For reference sake only, Defendant Eli Lilly, the Defendant aaiPharma Entities, and
5 Defendant Xanodyne shall be referred to herein individually by name or jointly as the "Innovator and
6 Brand Defendants," as these Defendants have, at various times as more fully set forth below, held the
7 approved New Drug Application ("NDA") for Darvocet and Darvon, brand-name prescription
8 medications containing propoxyphene as their sole or primary active ingredient for treatment of mild
9 to moderate pain.

10 35. Upon information and belief, other entities besides Defendant Eli Lilly, the Defendant
11 aaiPharma Entities and Defendant Xanodyne, including but not limited to one or more other named
12 Defendants or other entities not yet named, were involved in the testing, manufacture, marketing,
13 sales and/or distribution of brand-name Propoxyphene Products, and to the extent such an entity has
14 done so, then such entity is also a "Innovator and Brand Defendant," although Plaintiffs are still in
15 the process of investigating the extent of such relationships.

16 36. Defendant Eli Lilly first introduced propoxyphene to the United States market in 1957,
17 and held the approved NDAs for Darvocet (propoxyphene) and Darvon (propoxyphene plus
18 acetaminophen) until 2002. Defendant Eli Lilly is credited as Innovator of both Darvon and
19 Darvocet.

20 37. In 2002, Defendant Eli Lilly sold its approved NDAs for Darvocet and Darvon to the
21 Defendant aaiPharma Entities, subject to numerous restrictions, as set forth below. Pursuant to this
22 agreement, Eli Lilly retained an ongoing role and interest in the manufacture and marketing of
23 Darvocet and Darvon, and on information and belief, Eli Lilly also continued to manufacture generic
24 propoxyphene products for certain generic drug companies.

25 38. In 2007, the Defendant aaiPharma Entities, as part of their bankruptcy reorganization,
26 sold their approved NDAs for Darvocet and Darvon to Defendant Xanodyne.

27 39. The Innovator and Brand Defendants were in the business of and did (either directly or
28 indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest)

1 develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute
2 and introduce into interstate commerce throughout the United States, including in California and Los
3 Angeles County, Darvon and Darvocet for use as prescription pain management medications for mild
4 to moderate pain.

5 40. Upon information and belief, the Innovator and Brand Defendants entered into
6 contractual relationships related to the development, design, research, testing, licensing,
7 manufacturing, labeling, advertising, promotion, marketing, sale, distribution and/or introduction of
8 Darvon and Darvocet into interstate commerce throughout the United States, including within
9 California and Los Angeles County.

10 **GENERIC QUALITEST DEFENDANTS**

11 41. Defendant Qualitest Pharmaceuticals, Inc. ("Qualitest") was at all relevant times a
12 corporation organized under the laws of Alabama, with its principal place of business located at 130
13 Vintage Drive, Huntsville, Alabama 35811.

14 42. On or about November 7, 2007, Defendant Qualitest changed its name to Propst
15 Distribution, Inc. ("Propst"), but continued doing business under the name Qualitest Pharmaceuticals,
16 Inc.

17 43. Defendant Vintage Pharmaceuticals, Inc. ("Vintage") was at all relevant times a
18 corporation organized under the laws of Alabama, with its principal place of business located at 140
19 Vintage Drive, Huntsville Alabama 35811.

20 44. On or about November 5, 2007, Defendant Vintage changed its name to Propst
21 Distribution, Inc. ("Propst").

22 45. Defendant Propst was at all relevant times a corporation organized under the laws of
23 Alabama, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama
24 35811, and its reporting address located at 401 Meridian Street N, Huntsville, Alabama 35801.

25 46. On or about June 23, 2011, Defendant Qualitest and Defendant Propst changed their
26 legal names to Brenn Distribution, Inc. ("Brenn Distribution") and Defendant Vintage changed its
27 name to Brenn Manufacturing, Inc., but all continued doing business under the name Qualitest
28 Pharmaceuticals, Inc.

1 47. Defendant Brenn Distribution was at all relevant times a corporation organized under
2 the laws of Alabama, with its principle place of business located at 301 Meridian Street, Huntsville,
3 Alabama 35801.

4 48. Defendant, Brenn Manufacturing was at all relevant times a corporation organized
5 under the laws of Alabama, with its principle place of business located at 301 Meridian Street,
6 Huntsville, Alabama 35801.

7 49. Defendant Vintage Pharmaceuticals, LLC ("Vintage LLC") was at all relevant times a
8 corporation organized under the laws of Delaware, with its principal place of business located at 130
9 Vintage Drive, Huntsville, Alabama 35811, and may have also done business under the name
10 Qualitest Pharmaceuticals.

11 50. Defendant Generics International (US), Inc. ("Generics US") was at all relevant times
12 a corporation organized under the laws of Delaware, with its principal place of business located at
13 130 Vintage Drive, Huntsville, Alabama 35811.

14 51. Defendant Generics Bidco I, LLC ("Generics Bidco I") was at all relevant times a
15 corporation organized under the laws of Delaware, with its principal place of business located at 130
16 Vintage Drive, Huntsville, Alabama 35811.

17 52. Defendant Generics Bidco II, LLC ("Generics Bidco II") was at all relevant times a
18 corporation organized under the laws of Delaware, which may have had its principal place of
19 business located at 130 Vintage Drive, Huntsville, Alabama 35811.

20 53. Defendant Generics International (US Parent), Inc. ("Generics US Parent") was at all
21 relevant times a corporation organized under the laws of Delaware, with its principal place of
22 business located at 130 Vintage Drive, Huntsville, Alabama 35811.

23 54. Defendant Endo Pharmaceuticals, Inc. ("Endo") was at all relevant times a corporation
24 organized under the laws of Delaware, with its principal place of business located at 100 Endo
25 Boulevard, Chadds Ford, Pennsylvania 19317.

26 55. Defendant Endo Pharmaceuticals Holdings Inc. ("Endo Holdings") was at all relevant
27 times a corporation organized under the laws of Delaware, with its principal place of business located
28 at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

1 56. Defendant, Cornerstone BioPharma, Inc. ("Cornerstone BioPharma"), was at all
2 relevant times a corporation organized under the laws of the State of Nevada, with its principal place
3 of business located at 1255 Crescent Green Drive, Suite 250, Cary, NC 27511.

4 57. Defendant, Cornerstone BioPharma Holdings, Inc., ("Cornerstone Holdings"), was at
5 all relevant times a corporation organized under the laws of the State of Delaware, with its principal
6 place of business located at 1255 Crescent Green Drive, Suite 250, Cary, NC 27511.

7 58. Defendant Qualitest, Defendant Vintage, Defendant Propst, Defendant Brenn
8 Distribution, Defendant, Brenn Manufacturing, Defendant Vintage LLC, Defendant Generics US,
9 Defendant Generics Bidco I, Defendant Generics Bidco II, Defendant Generics US Parent, Defendant
10 Endo, Defendant Endo Holdings, Defendant Cornerstone BioPharma and Defendant, Cornerstone
11 Holdings shall be referred to herein individually by name or jointly as the "Generic Qualitest
12 Defendants."

13 59. At all relevant times, Defendant Generics US Parent owned Defendant Generics Bidco
14 I, Defendant Generics Bidco II and Defendant Generics US.

15 60. Until on or about December 1, 2010, Defendant Qualitest, Defendant Vintage,
16 Defendant Propst, Defendant Brenn Distribution, Defendant, Brenn Manufacturing and/or Defendant
17 Vintage LLC were owned by Defendant Generics US, Defendant Generics Bidco I, Defendant
18 Generics Bidco II and/or Defendant Generics US Parent.

19 61. On or about December 1, 2010, Defendant Endo Holdings acquired Defendant
20 Generics US, Defendant Generics Bidco I, Defendant Generics Bidco II and Defendant Generics US
21 Parent, and presumably indirectly acquired through one or all of them Defendant Qualitest,
22 Defendant Vintage, Defendant Propst, Defendant Brenn Distribution, Defendant, Brenn
23 Manufacturing and/or Defendant Vintage LLC.

24 62. The businesses of Defendant Qualitest, Defendant Vintage, Defendant Propst,
25 Defendant Brenn Distribution, Defendant, Brenn Manufacturing, and/or Defendant Vintage LLC may
26 have been combined thereafter into a single business unit with Defendant Endo.

27 63. Additionally, Cornerstone BioPharma entered into a certain Asset Purchase
28 Agreement and/or Manufacturing Agreement, as amended, with one or more of the other Qualitest

1 Defendants, including but not necessarily limited to Defendant, Vintage, LLC on or about July 20,
2 2004 for the sale, manufacture, marketing, supply, distribution and/or testing of Propoxyphene
3 Products including but not necessarily limited to Propoxyphene Napsylate/APAP 100 in 325mg and
4 500 mg forms.

5 64. Upon information and belief Defendant Cornerstone Holdings is a parent, subsidiary,
6 affiliate, or other related company through merger or otherwise with Defendant Cornerstone
7 BioPharma.

8 65. The extent to which Defendant Endo and/or Defendant Endo Holdings may have
9 assumed responsibility for the acts, omissions or liability of other Generic Qualitest Defendants,
10 contractually or otherwise, is unknown at this time, and Plaintiffs requires discovery as to this issue.

11 66. It is believed that at all relevant times, Defendant Qualitest, Defendant Vintage,
12 Defendant Propst, Defendant Brenn and/or Defendant Vintage LLC were the holders of approved
13 Abbreviated New Drug Applications ("ANDAs") for prescription pain management medications
14 containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

15 67. It is possible, however, that the ANDA for these generic drugs may have been owned
16 by another of the Generic Qualitest Defendants, or one or more of their subsidiaries, parents or
17 related entities, but Plaintiffs have been unable to determine this, despite diligent and reasonable
18 investigations.

19 68. Despite diligent and reasonable investigations, Plaintiff has been unable to determine
20 the exact relationship between and among the Generic Qualitest Defendants, but believe that each has
21 been in the business of, and been involved with, either directly or indirectly (through each other or
22 other subsidiaries, related entities, third parties, predecessors or successors in interest), developing,
23 designing, researching, testing, licensing, manufacturing, labeling, advertising, promoting, marketing,
24 selling, distributing and introducing into interstate commerce throughout the United States, including
25 in California and Los Angeles County, generic Propoxyphene Products for use as prescription pain
26 management medications.

69. Upon information and belief, the Generic Qualitest Defendants manufactured the majority of the Propoxyphene Products sold at national retailers, including CVS and Wal-Mart, as distributed by McKesson Defendants.

GENERIC TEVA DEFENDANTS

70. Defendant TEVA Biopharmaceuticals, Inc. ("TEVA Biopharmaceuticals") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 9410 Key West Avenue, Rockville, Maryland 20850-3345.

71. Defendant TEVA Pharmaceuticals USA, Inc. ("TEVA Pharmaceuticals") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

72. Defendant TEVA Biopharmaceuticals and Defendant TEVA Pharmaceuticals shall be collectively referred to as the "Generic TEVA Defendants."

73. It is believed that at all relevant times, one or a combination of the Generic TEVA Defendants were holders of approved Abbreviated New Drug Applications ("ANDAs") for prescription pain management medications containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

74. The Generic TEVA Defendants were in the business of and did (either directly or indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest) develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute and introduce into interstate commerce throughout the United States, including in California and Los Angeles County, generic Propoxyphene Products for use as prescription pain management medications for mild to moderate pain.

GENERIC MYLAN DEFENDANTS

75. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") was at all relevant times a corporation organized under the laws of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

1 83. Upon information and belief, Defendant Mallinckrodt Inc. ("Mallinckrodt") was at all
2 relevant times a corporation organized under the laws of Missouri or Delaware or New York, with its
3 principal place of business located at 675 McDonnell Boulevard., Hazelwood, Missouri 63042.

4 84. Defendants Covidien and Mallinckrodt are wholly-owned subsidiaries of Defendant
5 Covidien PLC.

6 85. Defendant Covidien PLC, Defendant Covidien and Defendant Mallinckrodt shall be
7 collectively referred to as the "Generic Covidien Defendants."

8 86. It is believed that at all relevant times, one or a combination of the Generic Covidien
9 Defendants were the holders of approved Abbreviated New Drug Applications ("ANDAs") for
10 prescription pain management medications containing propoxyphene that were generic formulations
11 of Darvocet and/or Darvon.

12 87. The Generic Covidien Defendants were in the business of and did (either directly or
13 indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest)
14 develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute
15 and introduce into interstate commerce throughout the United States, including in California and Los
16 Angeles County, generic Propoxyphene Products for use as prescription pain management
17 medications for mild to moderate pain.

18 **GENERIC WATSON DEFENDANTS**

19 88. Defendant Watson Pharmaceuticals, Inc. ("Watson" or "Generic Watson Defendant")
20 was at all relevant times a corporation organized under the laws of Nevada, with its principal place of
21 business located at 311 Bonnie Circle, Corona, California 92880-2882.

22 89. It is believed that at all relevant times, Defendant Watson was the holder of approved
23 Abbreviated New Drug Applications ("ANDAs") for prescription pain management medications
24 containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

25 90. Defendant Watson was in the business of and did (either directly or indirectly through
26 subsidiaries, related entities, third parties, predecessors or successors in interest) develop, design,
27 research, test, license, manufacture, label, advertise, promote, market, sell, distribute and introduce
28 into interstate commerce throughout the United States, including in California and Los Angeles

1 County, generic Propoxyphene Products for use as prescription pain management medications for
2 mild to moderate pain.

3 **GENERIC ABLE DEFENDANT**

4 91. Defendant Able Laboratories, Inc. ("Able") was at all relevant times a corporation
5 organized under the laws of Delaware, with its principal place of business located at 1 Able Drive,
6 Cranbury, New Jersey 08512-3609.

7 92. Defendant Able Laboratories, Inc., shall herein be referred to as "Generic Able
8 Defendant."

9 93. It is believed that at all relevant times, the Generic Able Defendant was a holder of
10 approved Abbreviated New Drug Applications ("ANDAs") for prescription pain management
11 medications containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

12 94. The Generic Able Defendants were in the business of and did (either directly or
13 indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest)
14 develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute
15 and introduce into interstate commerce throughout the United States, including in California and Los
16 Angeles County generic Propoxyphene Products for use as prescription pain management
17 medications for mild to moderate pain.

18 **GENERIC ARISTOS DEFENDANT**

19 95. Defendant Aristos Pharmaceuticals, Inc. ("Aristos" or "Generic Aristos Defendant")
20 was at all relevant times a corporation organized under the laws of Delaware, with its principal place
21 of business located at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518.

22 96. Defendant Aristos Pharmaceuticals, Inc. shall herein be referred to as "Generic Aristos
23 Defendant."

24 97. It is believed that at all relevant times, the Generic Aristos Defendant was the holder
25 of approved Abbreviated New Drug Applications ("ANDAs") for prescription pain management
26 medications containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

27 98. The Generic Aristos Defendants were in the business of and did (either directly or
28 indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest)

1 develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute
2 and introduce into interstate commerce throughout the United States, including in California and Los
3 Angeles County, generic Propoxyphene Products for use as prescription pain management
4 medications for mild to moderate pain.

5 **GENERIC DEFENDANTS**

6 99. For reference sake only, the Generic Qualitest Defendants, the Generic Covidien
7 Defendants, the Generic TEVA Defendants, the Generic Mylan Defendants, the Generic Watson
8 Defendants and any other Defendant and/or entity involved in the testing, manufacture, sale,
9 distribution and/or marketing of generic Propoxyphene Products shall be referred to herein
10 individually by name or jointly as the "Generic Defendants."

11 **PLAINTIFFS**

12 100. Plaintiffs are individuals who ingested Propoxyphene Products manufactured,
13 marketed, distributed, and sold by Defendants, and suffered severe cardiovascular injuries as a result
14 of said ingestion.

15 101. Plaintiff Margalit Corber is and was at all times relevant a resident and citizen of the
16 State of California. This Plaintiff purchased prescription Propoxyphene containing products on
17 various dates including but not necessarily limited to August 8, 2008, within the state of California.
18 This Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a
19 direct and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was
20 diagnosed an arrhythmia and/or other heart related injuries on or around August 28, 2009 within the
21 state of California. The Propoxyphene ingested by this Plaintiff was manufactured by one or more of
22 the Generic Defendants.

23 102. Plaintiff Rene Caro is and was at all times relevant a resident and citizen of the State
24 of California. This Plaintiff purchased prescription Propoxyphene containing products within the
25 state of California on or before November 2008 and on other dates. This Plaintiff ingested the
26 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
27 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with arrhythmia
28

1 and/or other heart related injuries on or around November 2008, within the state of California. The
2 Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Defendants.

3 103. Plaintiff Steve Dantzler is and was at all times relevant a resident and citizen of the
4 State of Alabama. This Plaintiff purchased prescription Propoxyphene containing products from 2000
5 to 2005 and other dates, within the state of Alabama. This Plaintiff ingested the Propoxyphene
6 containing medication at various times thereafter and as a direct and proximate result of this
7 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with bradycardia,
8 tachycardia and other heart related injuries on various dates from 2000 to 2005 and/or other heart
9 related injuries within the state of Alabama. The Propoxyphene ingested by this Plaintiff was
10 manufactured by one or more of the Defendants.

11 104. Plaintiff Linda Sowards is and was at all times relevant a resident and citizen of the
12 State of Alabama. This Plaintiff purchased prescription Propoxyphene containing products on various
13 dates including but not necessarily limited to November 3, 2010, within the state of Alabama. This
14 Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a direct
15 and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
16 with myocardial infarction and/or other heart related injuries on or around November 2010, within
17 the state of Alabama. The Propoxyphene ingested by this Plaintiff was manufactured by one or more
18 of the Generic Defendants.

19 105. Plaintiff Lori Huisman is and was at all times relevant a resident and citizen of the
20 State of Arizona. This Plaintiff purchased prescription Propoxyphene containing products within the
21 state of Arizona on or before July 31, 2009 and on other dates. This Plaintiff ingested the
22 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
23 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with tachycardia
24 resulting in pacemaker placement and/or other heart related injuries on or around July 31, 2009,
25 within the state of Arizona. The Propoxyphene ingested by this Plaintiff was manufactured by one or
26 more of the Defendants.

27 106. Plaintiff Johnny George Sr. is and was at all times relevant a resident and citizen of the
28 State of Arkansas. This Plaintiff purchased prescription Propoxyphene containing products within the

1 state of Arkansas on or before January 18, 2010 and on other dates. This Plaintiff ingested the
2 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
3 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with an arrhythmia
4 and/or other heart related injuries on or around January 18, 2010, within the state of Arkansas. The
5 Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Defendants.

6 107. Plaintiff Terry Perry is and was at all times relevant a resident and citizen of the State
7 of Arkansas. This Plaintiff purchased prescription Propoxyphene containing products on various
8 dates including but not necessarily limited to October 5, 2010, within the state of Arkansas. This
9 Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a direct
10 and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
11 with syncope and arrhythmia and/or other heart related injuries on or around November 1, 2010,
12 within the state of Arkansas. The Propoxyphene ingested by this Plaintiff was manufactured by one
13 or more of the Generic Defendants.

14 108. Plaintiff William Rackley is and was at all times relevant a resident and citizen of the
15 State of Arkansas. This Plaintiff purchased prescription Propoxyphene containing products on
16 various dates including but not necessarily limited to June 1, 2001, within the state of Arkansas. This
17 Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a direct
18 and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
19 with right bundle block, irregular heartbeat, and/or other heart related injuries on or around August
20 31, 2001, within the state of Arkansas. The Propoxyphene ingested by this Plaintiff was
21 manufactured by one or more of the Generic Defendants.

22 109. Plaintiff Angela Young is and was at all times relevant a resident and citizen of the
23 State of Arkansas. This Plaintiff purchased prescription Propoxyphene containing products within the
24 state of Arkansas on or before August 21, 2007. This Plaintiff ingested the Propoxyphene containing
25 medication at various times thereafter and as a direct and proximate result of this Plaintiff's
26 Propoxyphene use, this Plaintiff suffered and/or was diagnosed with an arrhythmia resulting in
27 pacemaker placement and/or other heart related injuries on or around August 27, 2007 within the
28

1 state of Arkansas. The Propoxyphene ingested by this Plaintiff was manufactured by one or more of
2 the Defendants.

3 110. Plaintiff Pamela Rodriguez is and was at all times relevant a resident and citizen of the
4 State of Colorado. This Plaintiff purchased prescription Propoxyphene containing products within the
5 state of Colorado in or before 1986 and other dates. This Plaintiff ingested the Propoxyphene
6 containing medication at various times thereafter and as a direct and proximate result of this
7 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with tachycardia and/or
8 other heart related injuries in or around 1986, within the state of Colorado. The Propoxyphene
9 ingested by this Plaintiff was manufactured by one or more of the Defendants.

10 111. Plaintiff Steven Syverson is and was at all times relevant a resident and citizen of the
11 State of Colorado. This Plaintiff purchased prescription Propoxyphene containing products within the
12 state of Colorado on or before 1992 and on other dates. This Plaintiff ingested the Propoxyphene
13 containing medication at various times thereafter and as a direct and proximate result of this
14 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with supraventricular
15 tachycardia, myocardial infarction, atrial fibrillation, and/or other heart related injuries on or around
16 1992, 2001, and 2002, within the state of Colorado. The Propoxyphene ingested by this Plaintiff was
17 manufactured by one or more of the Defendants.

18 112. Plaintiff Olga Caicoya is and was at all times relevant a resident and citizen of the
19 State of Florida. This Plaintiff purchased prescription Propoxyphene containing products within the
20 state of Florida on or before November 26, 2010 and on other dates. This Plaintiff ingested the
21 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
22 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with tachycardia
23 and/or other heart related injuries on or around November 26, 2010, within the state of Florida. The
24 Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Generic Defendants.

25 113. Plaintiff Janet Carroll is and was at all times relevant a resident and citizen of the State
26 of Florida. This Plaintiff purchased prescription Propoxyphene containing products within the state of
27 Florida in or before her injury in 2001 and on other dates. This Plaintiff ingested the Propoxyphene
28 containing medication at various times thereafter and as a direct and proximate result of this

1 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with syncope, arrhythmia
2 and/or other heart related injuries in or around 2001 within the state of Florida. The Propoxyphene
3 ingested by this Plaintiff was manufactured by one or more of the Defendants.

4 114. Plaintiff Rose Cash is and was at all times relevant a resident and citizen of the State
5 of Florida. This Plaintiff purchased prescription Propoxyphene containing products on various dates
6 within the state of Florida. This Plaintiff ingested the Propoxyphene containing medication at various
7 times thereafter and as a direct and proximate result of this Plaintiff's Propoxyphene use, this
8 Plaintiff suffered and/or was diagnosed with heart rhythm abnormalities and tachycardia in 2005, and
9 a heart attack in 2009, and other heart related injuries, within the state of Florida. The Plaintiff
10 ingested Propoxyphene Products manufactured by Defendants before suffering injuries as described
11 in this paragraph.

12 115. Plaintiff Ulad Celentano is and was at all times relevant a resident and citizen of the
13 State of Florida. This Plaintiff purchased prescription Propoxyphene containing products on various
14 dates within the state of Florida. This Plaintiff ingested the Propoxyphene containing medication at
15 various times thereafter and as a direct and proximate result of this Plaintiff's Propoxyphene use, this
16 Plaintiff suffered and/or was diagnosed with bradycardia necessitating a pacemaker installation, and
17 other heart related injuries, within the state of Florida. The Plaintiff ingested Propoxyphene Products
18 manufactured by Defendants before suffering injuries as described in this paragraph.

19 116. Plaintiff Virginia Costanzo is and was at all times relevant a resident and citizen of the
20 State of Florida. This Plaintiff purchased prescription Propoxyphene containing products on various
21 dates within the state of Florida. This Plaintiff ingested the Propoxyphene containing medication at
22 various times thereafter and as a direct and proximate result of this Plaintiff's Propoxyphene use, this
23 Plaintiff suffered and/or was diagnosed with tachycardia, prolonged QT and a borderline prolonged
24 PR interval on April 9, 2004 and/or other heart related injuries within the state of Florida. The
25 Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Defendants.

26 117. Plaintiff Kimberly Filligim is and was at all times relevant a resident and citizen of the
27 State of Florida. This Plaintiff purchased prescription Propoxyphene containing products within the
28 state of Florida on or before June 25, 2002 and on other dates. This Plaintiff ingested the

1 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
2 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with premature
3 ventricular contractions, bundle branch block and/or other heart related injuries on or around June 25,
4 2002, within the state of Florida. The Propoxyphene ingested by this Plaintiff was manufactured by
5 one or more of the Defendants.

6 118. Plaintiff Armeldia Smith is and was at all times relevant a resident and citizen of the
7 State of Florida. This Plaintiff purchased prescription Propoxyphene containing products on various
8 dates including but not necessarily limited to October 30, 2009, within the state of Florida. This
9 Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a direct
10 and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
11 with prolonged QT interval and/or other heart related injuries on or around February 2010, within the
12 state of Florida. The Propoxyphene ingested by this Plaintiff was manufactured by one or more of the
13 Generic Defendants.

14 119. Plaintiff Carla West is and was at all times relevant a resident and citizen of the State
15 of Florida. This Plaintiff purchased prescription Propoxyphene containing products, within the state
16 of Florida in or before 2003. This Plaintiff ingested the Propoxyphene containing medication at
17 various times thereafter and as a direct and proximate result of this Plaintiff's Propoxyphene use, this
18 Plaintiff suffered and/or was first diagnosed with an arrhythmia and subsequent supraventricular
19 tachycardia and/or other heart related injuries in or around 2003, within the state of Florida. The
20 Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Defendants.

21 120. Plaintiff Joanne Bierzynski individually and as next of kin to Decedent Eleanor
22 Wojcik brings this action individually and on behalf of next of kin and of Decedent Joanne
23 Bierzynski. Before this Decedent's death, she was at all times relevant a resident and citizen of the
24 State of Florida. This Decedent purchased prescription Propoxyphene containing products on various
25 dates including but not necessarily limited to January 15, 2004, within the state of Florida. This
26 Decedent ingested the Propoxyphene containing medication at various times thereafter and as a direct
27 and proximate result of this Decedent's Propoxyphene use, this Decedent suffered and/or was
28 diagnosed with cardiac standstill and an arrhythmia and/or other heart related injuries which directly

1 led to her death on or around February 2, 2004, within the state of Florida. The Propoxyphene
2 ingested by this Decedent was manufactured by one or more of the Generic Defendants.

3 121. Plaintiff Sharley Morris is and was at all times relevant a resident and citizen of the
4 State of Georgia. This Plaintiff purchased prescription Propoxyphene containing products within the
5 state of Georgia on or before December 28, 2007 and on other dates. This Plaintiff ingested the
6 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
7 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with bradycardia
8 with pacemaker placement and/or other heart related injuries on or around December 28, 2007,
9 within the state of Georgia. The Propoxyphene ingested by this Plaintiff was manufactured by one or
10 more of the Defendants.

11 122. Plaintiff Wyomia Timmons is and was at all times relevant a resident and citizen of
12 the State of Georgia. This Plaintiff purchased prescription Propoxyphene containing products on
13 various dates including but not necessarily limited to October 9, 2010, within the state of Georgia.
14 This Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a
15 direct and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was
16 diagnosed with an irregular heartbeat and/or other heart related injuries on or around November 2010,
17 within the state of Georgia. The Propoxyphene ingested by this Plaintiff was manufactured by one or
18 more of the Generic Defendants.

19 123. Plaintiff Dean Reinking is and was at all times relevant a resident and citizen of the
20 State of Hawaii. This Plaintiff purchased prescription Propoxyphene containing products within the
21 state of Hawaii in or before 2004, 2008 and other dates. This Plaintiff ingested the Propoxyphene
22 containing medication at various times thereafter and as a direct and proximate result of this
23 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with tachycardia in or
24 about 2004, myocardial infarction in or about 2008, and/or other heart related injuries within the state
25 of Hawaii. The Propoxyphene ingested by this Plaintiff was manufactured by one or more of the
26 Defendants.

27 124. Plaintiff Daniel Thorne is and was at all times relevant a resident and citizen of the
28 State of Illinois. This Plaintiff purchased prescription Propoxyphene containing products within the

1 state of Illinois on or before November 15, 2009 and other dates. This Plaintiff ingested the
2 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
3 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with
4 supraventricular tachycardia, prolonged QT interval and/or other heart related injuries on or around
5 November 15, 2009, within the state of Illinois. The Propoxyphene ingested by this Plaintiff was
6 manufactured by one or more of the Generic Manufacturers.

7 125. Plaintiff Wendelen Ashby is and was at all times relevant a resident and citizen of the
8 State of Indiana. This Plaintiff purchased prescription Propoxyphene containing products on various
9 dates including but not necessarily limited to May 2, 2004, June 23, 2004, and September 19, 2004,
10 within the state of Indiana. This Plaintiff ingested the Propoxyphene containing medication at various
11 times thereafter and as a direct and proximate result of this Plaintiff's Propoxyphene use, this
12 Plaintiff suffered and/or was diagnosed with an arrhythmia and/or other heart related injuries in or
13 around 2004 within the state of Indiana. The Propoxyphene ingested by this Plaintiff was
14 manufactured by one or more of the Generic Defendants.

15 126. Plaintiff Carmen Bedford is and was at all times relevant a resident and citizen of the
16 State of Indiana. This Plaintiff purchased prescription Propoxyphene containing products on various
17 dates including but not necessarily limited to July 17, 2008, within the state of Indiana. This Plaintiff
18 ingested the Propoxyphene containing medication at various times thereafter and as a direct and
19 proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
20 with heart arrhythmia, bradycardia, and tachycardia and/or other heart related injuries on or around
21 2008, within the state of Indiana. The Propoxyphene ingested by this Plaintiff was manufactured by
22 one or more of the Generic Defendants.

23 127. Plaintiff Claude Commodore is and was at all times relevant a resident and citizen of
24 the State of Indiana. This Plaintiff purchased prescription Propoxyphene containing products within
25 the state of Indiana on or before 2006 and on other dates. This Plaintiff ingested the Propoxyphene
26 containing medication at various times thereafter and as a direct and proximate result of this
27 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with an arrhythmia and
28

1 tachycardia and/or other heart related injuries in or around 2006, within the state of Indiana. The
2 Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Generic Defendants.

3 128. Plaintiff James Henson is and was at all times relevant a resident and citizen of the
4 State of Indiana. This Plaintiff purchased prescription Propoxyphene containing products on various
5 dates including but not necessarily limited to August 26, 2010, within the state of Indiana. This
6 Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a direct
7 and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
8 with bradycardia resulting in pacemaker placement and/or other heart related injuries in or around
9 April 2010, within the state of Indiana. The Propoxyphene ingested by this Plaintiff was
10 manufactured by one or more of the Generic Defendants.

11 129. Plaintiff Nancy Locke is and was at all times relevant a resident and citizen of the
12 State of Indiana. This Plaintiff purchased prescription Propoxyphene containing products on various
13 dates including but not necessarily limited to June 7, 2010, within the state of Indiana. This Plaintiff
14 ingested the Propoxyphene containing medication at various times thereafter and as a direct and
15 proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
16 with right bundle branch block and syncope and/or other heart related injuries on or around June 7,
17 2010, within the state of Indiana. The Propoxyphene ingested by this Plaintiff was manufactured by
18 one or more of the Generic Defendants.

19 130. Plaintiff Mildred Scott is and was at all times relevant a resident and citizen of the
20 State of Indiana. This Plaintiff purchased prescription Propoxyphene containing products, within the
21 state of Indiana in or before May 2010 and on other dates. This Plaintiff ingested the Propoxyphene
22 containing medication at various times thereafter and as a direct and proximate result of this
23 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with arrhythmia,
24 tachycardia and/or other heart related injuries in or around May 2010, within the state of Indiana. The
25 Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Defendants.

26 131. Plaintiff Billie Burnett is and was at all times relevant a resident and citizen of the
27 State of Kansas. This Plaintiff purchased prescription Propoxyphene containing products within the
28 state of Kansas in or before 2002 and on other dates. This Plaintiff ingested the Propoxyphene

1 containing medication at various times thereafter and as a direct and proximate result of this
2 Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was first diagnosed with an arrhythmia
3 resulting in pacemaker placement and/or other heart related injuries in or around 2002, within the
4 state of Kansas. The Propoxyphene ingested by this Plaintiff was manufactured by one or more of the
5 Defendants.

6 132. Plaintiff Sheena Hall is and was at all times relevant a resident and citizen of the State
7 of Maine. This Plaintiff purchased prescription Propoxyphene containing products on various dates
8 including but not necessarily limited to 2009, within the state of Maine. This Plaintiff ingested the
9 Propoxyphene containing medication at various times thereafter and as a direct and proximate result
10 of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed with arrhythmia
11 and/or other heart related injuries on or around 2009, within the state of Maine. The Propoxyphene
12 ingested by this Plaintiff was manufactured by one or more of the Defendants.

13 133. Plaintiff Brenda Roberge individually and as next of kin to Decedent Ernest Roberge
14 brings this action individually and on behalf of next of kin and of Decedent Ernest Roberge. Before
15 this Decedent's death, he was at all times relevant a resident and citizen of the State of Maine. This
16 Decedent purchased prescription Propoxyphene containing products within the state of Maine on or
17 before May 2, 2010 and on other dates. This Decedent ingested the Propoxyphene containing
18 medication at various times thereafter and as a direct and proximate result of this Decedent's
19 Propoxyphene use, this Decedent suffered and/or was diagnosed with cardiac arrest, cardiomyopathy,
20 and/or other heart related injuries which directly led to his death on or around May 2, 2010, within
21 the state of Maine. The Propoxyphene ingested by this Decedent was manufactured by one or more
22 of the Defendants.

23 134. Plaintiff Deborah Woodsum is and was at all times relevant a resident and citizen of
24 the State of Maine. This Plaintiff purchased prescription Propoxyphene containing products on
25 various dates including but not necessarily limited to October 7, 2008, within the state of Maine. This
26 Plaintiff ingested the Propoxyphene containing medication at various times thereafter and as a direct
27 and proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
28 with arrhythmia and/or other heart related injuries on or around October 7, 2008, within the state of

1 Maine. The Propoxyphene ingested by this Plaintiff was manufactured by one or more of the Generic
2 Defendants.

3 135. Plaintiff Richard Pascuito is and was at all times relevant a resident and citizen of the
4 State of Massachusetts. This Plaintiff purchased prescription Propoxyphene containing products
5 within the state of Massachusetts on or before April 28, 1992 an on other dates. This Plaintiff
6 ingested the Propoxyphene containing medication at various times thereafter and as a direct and
7 proximate result of this Plaintiff's Propoxyphene use, this Plaintiff suffered and/or was diagnosed
8 with ventricular fibrillation, cardiac arrest and/or other heart related injuries on or around April 28,
9 1992, within the state of Massachusetts. The Propoxyphene ingested by this Plaintiff was
10 manufactured by one or more of the Defendants.

11 136. Upon information and belief all of Plaintiff's injuries, as set forth in the preceding
12 paragraphs were directly and proximately caused by Plaintiff's ingestion of propoxyphene products.

13 137. The medical treatment and injuries described above are not necessarily a full and
14 complete description of each Plaintiff's injuries, as Plaintiff may have or did incur further treatment
15 and injuries not specifically set forth herein.

16 FACTUAL BACKGROUND

17 18 I. THE DANGERS AND DUBIOUS EFFECTIVENESS OF PROPOXYPHENE 19 PRODUCTS

20 A. Propoxyphene is a dangerous, ineffective drug.

21 138. Propoxyphene is a centrally-acting opiate analgesic that is structurally related to
22 methadone.

23 139. Propoxyphene is a pain reliever used to treat mild to moderate pain.

24 140. Propoxyphene is marketed in two chemical forms (propoxyphene hydrochloride and
25 propoxyphene napsylate), and is sold both as a single chemical entity and also in combination with
26 either acetaminophen or aspirin.

27 141. Branded products with the name "Darvocet" contain both propoxyphene and
28 acetaminophen.

1 142. Branded products with the name "Darvon" do not contain acetaminophen.

2 143. In 1971, Eli Lilly conducted seven identically designed efficacy trials for
3 propoxyphene, six of which demonstrated that propoxyphene alone was not significantly superior to
4 placebo. The trials showed, in contrast, that acetaminophen was significantly superior to placebo.

5 144. Propoxyphene also has been plagued by concerns of its potential toxicity for decades.

6 145. for instance, in as early as 1978, the Health Research Group filed a Citizen Petition to
7 the FDA requesting the recall of Darvon, claiming it was a dangerous drug of questionable
8 effectiveness.

9 146. Non-clinical studies conducted in response to the 1978 Citizen Petition supported the
10 hypothesis of certain clinical findings that deaths due to overdoses of propoxyphene could be due to
11 cardiotoxicity from propoxyphene.

12 147. Upon information and belief, Defendants knew of the risks and questionable
13 effectiveness of Propoxyphene Products for decades and failed to convey those concerns to the public
14 and/or properly investigate the concerns.

15 148. According to the FDA, in 2009, approximately ten million people in the United States
16 received prescriptions for Propoxyphene Products.

17 149. However, propoxyphene, when taken as prescribed and intended, causes and
18 contributes to a greatly increased risk of serious and dangerous side effects including, without
19 limitation, heart arrhythmias, myocardial infarctions, other adverse cardiovascular events and/or
20 sudden death.

21 150. These unique and dangerous risks are not present with other practical and medically-
22 feasible alternate pain management medications that do not contain propoxyphene.

23 151. The FDA's adverse event data has confirmed that staggering, serious adverse events
24 have been associated with propoxyphene-containing drugs, including but not limited to heart
25 arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial infarctions and/or sudden
26 death.

27 **B. Great Britain and Europe Withdrew Propoxyphene Products.**
28

1 152. In January 2005, health officials in Great Britain called for a phased withdrawal of
2 propoxyphene-containing products because of concerns about the cardiac effects associated with the
3 use of propoxyphene.

4 153. In the announcement of the phased withdrawal of propoxyphene-containing products
5 in Great Britain, health officials stated that "it has not been possible to identify any patient group in
6 whom the risk benefit (ratio) may be positive."

7 154. British officials further stated that propoxyphene's efficacy "is poorly established and
8 the risk of toxicity in overdose, both accidental and deliberate, is unacceptable" even in "normal
9 therapeutic doses."

10 155. In other words, the British officials found, as Plaintiff herein alleges, that
11 propoxyphene is a dangerous drug even in standard therapeutic doses.

12 156. In addition, a 2009 study titled "Effect of Withdrawal of Co-Proxamol
13 [propoxyphene-acetaminophen] on Prescribing and Deaths from Drug Poisoning in England and
14 Wales: Time Series Analysis" concluded that the phased withdrawal of propoxyphene-containing
15 products in Great Britain resulted in a substantial decline in suicides and accidental deaths involving
16 such products during the phased withdrawal.

17 157. In June 2009, the European Medicines Agency ("EMA") recommended that the
18 marketing authorizations for propoxyphene-containing medications be withdrawn across the
19 European Union because of safety concerns.

20 158. When deciding to ban propoxyphene-containing medications, the EMA stated that
21 "the available evidence suggests that the combination of propoxyphene and acetaminophen (as in
22 Tylenol) is no more effective than acetaminophen on its own."

23 159. The EMA further stated that "the benefits of all medicines containing propoxyphene,
24 either on its own or in combination, do not outweigh their risks."

25
26 **C. The FDA called for the recall of Propoxyphene Products after**
27 **determining that their risks outweighed their benefits.**
28

1 160. A 2008 report titled "Drugs Identified in Deceased Persons by Florida Medical
2 Examiners" reported that propoxyphene caused eighty deaths in Florida during 2008.

3 161. A 2009 report titled "Drugs Identified in Deceased Persons by Florida Medical
4 Examiners," produced by the Florida Department of Law Enforcement, demonstrated that
5 propoxyphene caused 460 deaths in Florida alone from 2003 through 2007. This death toll equates to
6 4.2 causally-related deaths per 100,000 propoxyphene prescriptions, significantly higher than
7 comparable ratios for alternative drugs examined in the report, such as tramadol, which caused only
8 2.2 deaths per 100,000 prescriptions. A drug was only indicated as the cause of death when, after
9 examining all the evidence and the autopsy and toxicology results, the medical examiner determined
10 the drug played a causal role in the death.

11 162. In 2009, data from the Drug Abuse Warning Network (DAWN) presented to an FDA
12 Advisory Committee demonstrated that in seven of the eight states examined, the number of drug-
13 related deaths per 100,000 prescriptions was higher for propoxyphene than for tramadol or
14 hydrocodone from 2004 through 2007. In the eighth state, propoxyphene resulted in more deaths per
15 100,000 prescriptions than hydrocodone and only slightly less than tramadol.

16 163. Despite overwhelming evidence of the risks of all propoxyphene-containing
17 medications, their withdrawal from European markets, and evidence that Propoxyphene Products
18 were no more effective than Tylenol, Defendants continued to actively market, produce and distribute
19 Propoxyphene Products in the United States, causing injuries that included but were not limited to
20 heart arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial infarctions, and/or
21 sudden death.

22 164. In light of these concerns, public interest groups petitioned for an investigation into
23 whether propoxyphene-containing drugs were linked to serious and potentially fatal heart
24 arrhythmias.

25 165. In 2009, in light of these concerns and renewed efforts to recall Propoxyphene
26 Products, the FDA Advisory Committee voted against the continued marketing of propoxyphene-
27 containing products.

1 166. Although the FDA did not follow the Advisory Committee's recall recommendation at
2 that time, it did order Xanodyne to conduct clinical trials to assess the potential for cardiotoxicity
3 associated with propoxyphene use, to prepare a Medication Guide ("MedGuide") as part of a Risk
4 Evaluation and Minimization Strategy ("REMS") to highlight important safeguards for use of the
5 drug, and to issue a Public Health Advisory to underscore safety issues.

6 167. The FDA also ordered Xanodyne to include a "Black Box" warning on its label,
7 effective July 9, 2009, concerning the risk of fatal overdose, the relevant portion of which states as
8 follows:

9 There have been numerous cases of accidental and intentional overdose with
10 propoxyphene products either alone or in combination with other CNS
11 depressants, including alcohol. Fatalities within the first hour of overdosage
12 are not uncommon. Many of the propoxyphene-related deaths have occurred
13 in patients with previous histories of emotional disturbances or suicidal
14 ideation/attempts and/or concomitant administration of sedatives,
15 tranquilizers, muscle relaxants, antidepressants, or other CNS-depressant
16 drugs. Do not prescribe propoxyphene for patients who are suicidal or have a
17 history of suicidal ideation.

18 168. The FDA also required Xanodyne to add a Clinical Pharmacology section to its label
19 to include the following warning about dangers associated with propoxyphene:

20 Propoxyphene is a centrally acting opiate analgesic. In vitro studies
21 demonstrated propoxyphene and the metabolite norpropoxyphene inhibit
22 sodium channels (local anesthetic effect) with norpropoxyphene being
23 approximately 2-fold more potent than propoxyphene and propoxyphene
24 approximately 10-fold more potent than lidocaine. Propoxyphene and
25 norpropoxyphene inhibit the voltage-gated potassium current carried by
26 cardiac rapidly activating delayed rectifier (hERG channels) with
27 approximately equal potency. It is unclear if the effects on ion channels occur
28 within therapeutic dose range.

29 169. The FDA also required Xanodyne to add a Special Populations section to its label to
30 include the following warning about the special dangers propoxyphene poses to geriatric patients:

31 After oral administration of propoxyphene in elderly patients (70-78 years),
32 much longer half-lives of propoxyphene and norpropoxyphene have been
33 reported (propoxyphene 13 to 35 h, norpropoxyphene 22 to 41 h). In addition,

the AUC was an average of 3-fold higher and the Cmax was an average of 2.5-fold higher in the elderly when compared to a younger (20-28 years) population. Longer dosage intervals may be considered in the elderly because the metabolism of propoxyphene may be reduced in this patient population. After multiple oral doses of propoxyphene in elderly patients (70-78 years), the Cmax of the metabolite (norpropoxyphene) was increased 5-fold.

170. Similarly, the FDA also required Xanodyne to add the following warning about the special dangers propoxyphene poses to elderly patients to the Precautions section of its label:

Clinical studies of DARVOCET-N did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. However, postmarketing reports suggest that patients over the age of 65 may be more susceptible to CNS-related side effects. Therefore, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Decreased total daily dosage should be considered (See DOSAGE and ADMINISTRATION).

171. The FDA also required Xanodyne to add the following warnings about propoxyphene's potential for abuse and dependence in a new Drug Abuse and Dependence section of its label:

Controlled Substance

DARVOCET-N is a Schedule IV narcotic under the U.S. Controlled Substances Act. DARVOCET-N can produce drug dependence of the morphine type, and therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration. DARVOCET-N should be prescribed and administered with the same degree of caution appropriate to the use of other narcotic-containing medications.

Abuse

Since DARVOCET-N is a mu-opioid agonist, it may be subject to misuse, abuse, and addiction. Addiction to opioids prescribed for pain management has not been estimated. However, requests for opioids from opioid-addicted patients occur. As such, physicians should take appropriate care in prescribing DARVOCET-N.

Dependence

Opioid analgesics may cause psychological and physical dependence. Physical dependence results in withdrawal symptoms in patients who abruptly discontinue the drug after long term administration. Also, symptoms of withdrawal may be precipitated through the administration of drugs with mu-opioid antagonist activity, e.g., naloxone or mixed agonist/antagonist analgesics (pentazocine, butorphanol, nalbuphine, dezocine). (See also OVERDOSAGE section). Physical dependence usually does not occur to a clinically significant degree, until after several weeks of continued opioid usage. Tolerance, in which increasingly larger doses are required to produce the same degree of analgesia, is usually manifested by a shortened duration of an analgesic effect and subsequently, by decreases in the intensity of analgesia.

In chronic pain patients, and in opioid-tolerance cancer patients, the administration of DARVOCET-N should be guided by the degree of tolerance manifested and the doses needed to adequately relieve pain.

The severity of the DARVOCET-N abstinence syndrome may depend on the degree of physical dependence. Withdrawal is characterized by rhinitis, myalgia, abdominal cramping, and occasional diarrhea. Most observable symptoms disappear in 5 to 14 days without treatment; however, there may be a phase of secondary or chronic abstinence which may last for 2 to 6 months characterized by insomnia, irritability, and muscular aches. The patient may be detoxified by gradual reduction of the dose. Gastrointestinal disturbances or dehydration should be treated with supportive care.

172. Finally, the FDA also required Xanodyne to add the following warnings about tolerance and dependence in the Precautions section of its label:

Tolerance and Physical Dependence

Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Physical dependence is manifested by withdrawal symptoms after abrupt discontinuation of a drug or upon administration of an antagonist. Physical dependence and tolerance are not unusual during chronic opioid therapy.

The opioid abstinence or withdrawal syndrome is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. In general, opioids should not be abruptly discontinued (see DOSAGE AND ADMINISTRATION: Cessation of Therapy).

1 If DARVOCET-N is abruptly discontinued in a physically dependent patient,
2 an abstinence syndrome may occur (See DRUG ABUSE AND
3 DEPENDENCE). If signs and symptoms of withdrawal occur, patients
4 should be treated by reinstitution of opioid therapy followed by gradual
5 tapered dose reduction of DARVOCET-N combined with symptomatic
6 support (see DOSAGE AND ADMINISTRATION: Cessation of Therapy).

7 173. Upon information and belief, Xanodyne did not comply with the FDA's mandate to
8 prepare the MedGuide or issue the Public Health Advisory.

9 174. Upon information and belief, Xanodyne also did not timely implement the Black Box
10 warning or revise the labels for Darvocet or Darvon.

11 175. Upon information and belief, Xanodyne also did not publish the information in the
12 Physicians' Desk Reference ("PDR"), the primary source of drug warning information for physicians.

13 176. Upon information and belief, Xanodyne also did not communicate the information to
14 prescribing physicians in Dear Health Care Professional letters or by other means.

15 177. The FDA mandate likewise effectively required the Generic Defendants to issue the
16 Black Box warning and label changes, but upon information and belief, the Generic Defendants did
17 not timely implement the Black Box warning or revise the labels for their Propoxyphene Products, or
18 publish the information in the PDR, or communicate the information to prescribing physicians in
19 Dear Health Care Professional letters or by other means.

20 178. Xanodyne did, however, follow part of the FDA mandate by starting to conduct a
21 multiple-ascending dose (MAD) study in July 2009, which confirmed that even when taken at
22 recommended doses, propoxyphene can cause significant changes to the electrical activity of the
23 heart that can be seen on an electrocardiogram (ECG), such as prolonged PR intervals, widened QRS
24 complexes, and prolonged QT intervals.

25 179. An ECG is a recording of the electrical activity generated by the heart as it undergoes
26 depolarization and repolarization, which is the process that causes the muscles in the heart to contract
27 rhythmically and pump blood throughout the body.

28 180. The different waves that comprise the ECG, including the PR intervals, QRS
complexes, and QT intervals, represent the sequence of depolarization and repolarization of the atria

1 and ventricles. Abnormalities in the ECG indicate abnormalities in the electrical activity of the heart,
2 specifically the depolarization and repolarization process.

3 181. Changes in the electrical activity of the heart can increase the risk for serious
4 abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

5 182. Propoxyphene's principal metabolite, norpropoxyphene, is a Sodium channel and
6 hERG channel blocker. Blockage of either of these channels can lead to changes in the electrical
7 activity of the heart and other cardiac injuries.

8 183. The FDA concluded that the safety risks of propoxyphene, including the negative
9 effects of propoxyphene on the electrical activity of the heart, outweigh its benefit for pain relief.

10 184. On November 19, 2010, the FDA announced that Xanodyne had agreed to stop
11 marketing its Propoxyphene Products in the United States.

12 185. Also on November 19, 2010, the FDA requested that the generic manufacturers also
13 remove their Propoxyphene Products.

14 186. Also on November 19, 2010, the FDA advised health care professionals to stop
15 prescribing and dispensing Propoxyphene Products, and to ask their patients to stop taking those
16 drugs.

17 187. In its news release on November 19, 2010, the FDA said that the data showed "that
18 even when taken at recommended doses, propoxyphene causes significant changes to the electrical
19 activity of the heart" and that the changes in electrical activity of the heart "can increase the risk for
20 serious abnormal heart rhythms that have been linked to serious adverse events, including sudden
21 death."

22 **II. DEFENDANTS' NEGLIGENT AND WRONGFUL MARKETING,**
23 **DISTRIBUTING AND SALE OF DEFECTIVELY DESIGNED**
PROPOXYPHENE PRODUCTS

24 188. At all relevant time, Eli Lilly knew or should have known that Propoxyphene Products
25 were defectively designed.

26 189. As discussed above, in 1978, the Health Research Group filed a Citizen Petition with
27 the FDA seeking the recall of Propoxyphene Products.
28

1 190. Upon information and belief, the FDA rejected the 1978 recall in large part because of
2 Eli Lilly's vocal and ultimately successful campaign, in which it made numerous false statements
3 regarding the safety and efficacy of Propoxyphene Products, even though it knew or should have
4 known that such statements were false.

5 191. Upon information and belief, Eli Lilly also made commitments to the FDA about the
6 manner in which it would market its Propoxyphene Products to address safety concerns, but failed to
7 live up to these commitments.

8 192. For example, a key factor in the FDA's decision to reject changing the regulatory
9 status of Propoxyphene Products was Eli Lilly's commitment to an educational program to sensitize
10 prescribers and patients to the hazards of propoxyphene products.

11 193. Upon information and belief, Eli Lilly not only failed to emphasize the user warnings
12 in the majority of its physician visits, but also converted that "educational program" into a marketing
13 initiative.

14 194. At all relevant times, Xanodyne focused its sales on pain management products,
15 including Darvocet and Darvon, because the area of pain management offers attractive commercial
16 opportunities in significant markets in the United States.

17 195. At all relevant times, Xanodyne affirmatively decided not to take part in full discovery
18 research of its products because it was and is more beneficial for it to advance products more quickly
19 through abbreviated developmental pathways in order to decrease the time and cost of bringing a new
20 drug to market.

21 196. At all relevant times, Xanodyne extensively marketed Darvocet and Darvon as safe
22 and effective treatments for pain to induce their widespread use, and has received significant profits
23 from the sale of those drugs.

24 197. Similar to Eli Lilly's efforts to defeat the 1978 Propoxyphene Products recall request,
25 as discussed above, Xanodyne also acted to defeat petitions to the FDA to recall Propoxyphene
26 Products.

27 198. Upon information and belief, in April, 2006, Xanodyne made false and misleading
28 statements that it knew or should have known were false and misleading concerning the safety and

1 effectiveness of Propoxyphene Products to the FDA in opposition to a 2006 Citizen Petition
2 requesting the recall of Propoxyphene Products.

3 199. Upon information and belief, Xanodyne also failed to disclose information that was
4 inconsistent with allegations made in the Citizen Petition.

5 200. Additionally, upon information and belief, Xanodyne made a presentation at the
6 FDA's Joint Meeting of the Aesthetic and Life Support Drugs Advisory Committee and Drug Risk
7 Management Committee on January 30, 2009 concerning the same 2006 Citizen Petition to recall
8 Propoxyphene Products, in which it made the following false representations, among others, about
9 Propoxyphene Products, even though it knew such statements to be false:

- 10 a. that "Darvon and its combinations were effective analgesics";
11 b. that Propoxyphene Products are "superior to placebo";
12 c. that "Propoxyphene products have a long history in the US of safe and
13 effective use as labeled"; and
14 d. that "Petitioner [i.e., Public Citizen in its 2006 FDA Citizen Petition to recall
15 Darvocet] presents no credible scientific evidence that propoxyphene drugs
16 present an imminent hazard to public health or that they are unsafe and
17 ineffective when used according to approved labeling."

18 201. Upon information and belief, it is believed that the Generic Defendants likewise
19 represented that their Propoxyphene Products were safe and effective for pain management in order
20 to induce their widespread use, and have received significant profits from their sales of those drugs.

21 202. Defendants knew or should have known of the dangers associated with Propoxyphene
22 Products, including but not limited to the risks of serious abnormal heart rhythms that may cause
23 serious adverse events, including death.

24 203. Additionally, or in the alternative, Defendants should have started to investigate the
25 link between Propoxyphene Products and cardiac effects significantly before the FDA ordered such
26 an investigation.

27 204. Had Defendants investigated propoxyphene safety on a timely basis, the associated
28 risks would have been confirmed in time to prevent Plaintiffs from being prescribed or filling

1 prescriptions for Propoxyphene Products, from ingesting or continuing to ingest Propoxyphene
2 Products, and from suffering injuries as a result of those ingestions.

3 205. Independent of this, before Plaintiffs were injured by ingesting Propoxyphene
4 Products, there was a wealth of scientific and medical evidence available to Defendants – but not to
5 Plaintiffs or their prescribing physicians – to correlate the use of those drugs with the increased risk
6 of developing serious adverse cardiovascular effects, potentially resulting in death, which made those
7 drugs unreasonably dangerous to consumers.

8 206. Despite what Defendants knew or should have known through the sources cited above,
9 they continued to manufacture and market and sell Propoxyphene Products.

10 207. Upon information and belief, despite what Defendants knew or should have known
11 through the sources cited above, they failed to provide adequate information to the general public or
12 the health care community – including Plaintiffs and their prescribing physicians – about the
13 correlation between the use of Propoxyphene Products and the increased risk of developing
14 serious adverse cardiovascular effects, potentially resulting in death, which made those drugs
15 unreasonably dangerous to consumers due to the following:

- 16
- 17 a. Defendants failed to convey the warnings in a method reasonably calculated to
18 notify the public and the health care community of its risks.
- 19 b. Defendants failed to convey the warning in a location or manner reasonably
20 calculated to notify the public and the health care community of its risks.
- 21 c. Defendants failed to convey the warning by use of facts or information that
22 were known about the risks of Propoxyphene Products.
- 23 d. Defendants failed to convey warnings in a manner that was clear, accurate and
24 properly portrayed the intensity of the risks posed by Propoxyphene Products.
- 25 e. Defendants failed to provide “Dear Health Care Professional” letters to the
26 health care community, as authorized by the FDA at 21 CFR 201.100(d)(1), at
27 all and/or in a manner reasonably calculated to convey the risks associated
28 with Propoxyphene Products.
- f. Defendants failed to provide “Dear Health Care Professional” letters after the
inclusion of warning label changes approved and/or required by the FDA,

1 including but not necessarily limited to the 2009 label change requiring a
2 "Black Box" warning, as discussed above.

- 3 g. Defendants failed to take reasonable steps to otherwise notify the public and
4 the health care community of the inclusion of warning label changes approved
5 and/or required by the FDA, including but not necessarily limited to the 2009
6 label change requiring a "Black Box" warning, as discussed above.
- 7 h. The Innovator and Brand Defendants failed to recommend to the FDA through
8 the Changes Being Effectuated ("CBE") process that branded Propoxyphene
9 Products include a warning identical or similar to the 2009 "Black Box"
10 warning since Defendants knew or should have known of the risks conveyed in
11 the "Black Box" warning for years prior to its inclusion in the warning label.
- 12 i. Xanodyne failed to properly notify the public and the health care community
13 about the health risks conveyed in the 2009 "Black Box" warning even though
14 the FDA specifically instructed them to do so.
- 15 j. Upon information and belief, Xanodyne continued to promote brand-name
16 Propoxyphene Products as safe and effective even though it knew this was not
17 correct, before and even after, the FDA ordered Xanodyne to include the
18 "Black Box" warning in 2009.
- 19 k. Upon information and belief, the Generic Defendants failed to update their
20 labels with certain label changes that the FDA approved and/or ordered for use
21 by the Innovator and Brand Defendants, although Plaintiff must conduct
22 discovery to determine the extent of this failure since the Generic Defendants'
23 warning labels are not included in the Physician's Desk Reference.
- 24 l. Defendants could have and should have requested stronger warnings for
25 Propoxyphene Products, which the FDA could have then ordered to be
26 included in the label without the need to undertake negotiations with the
27 branded manufacturer.

28 208. As stated above, upon information and belief, Defendants failed to adequately convey
or warn the public and the health care community as to the risks associated with Propoxyphene
Products, though discovery is necessary as to these issues since this information is, in large part, in
control of Defendants.

209. Upon information and belief, Defendants continued to promote and affirmatively
claim that Propoxyphene Products are safe and effective, although they knew or should have known
this was not the case.

1 210. At least in part, the extent, dates and methods by which Defendants continued to
2 promote the safety and effectiveness of Propoxyphene Products is not fully known, as this
3 information is in the control of Defendants, and discovery is necessary to obtain this information.

4 211. Had Defendants stopped selling Propoxyphene Products when they knew or should
5 have known about the increased and unreasonably dangerous risks associated with their use,
6 Plaintiffs would not have been prescribed or would not have filled prescriptions for Propoxyphene
7 Products, would not have ingested or would have stopped ingesting them, and would not have
8 suffered injuries resulting from those ingestions.

9 212. Had the general public or the health care community – including Plaintiffs and their
10 prescribing physicians – been adequately advised of the risks associated with the use of
11 Propoxyphene Products, Plaintiffs would not have been prescribed or would not have filled
12 prescriptions for Propoxyphene Products, would not have ingested or would have stopped ingesting
13 them, and would not have suffered injuries resulting from those ingestions.

14
15 **III. INNOVATOR AND BRAND DEFENDANTS' OWNERSHIP AND**
16 **TRANSFERS OF THE DARVOCET AND DARVON NDAs**

17 **A. Eli Lilly owned and then transferred the Darvocet and Darvon NDAs.**

18 213. Prior to 2002, Eli Lilly owned all rights to Darvocet and Darvon, including the NDAs
19 to sell those products. It had held these rights since FDA approval of Darvon (in 1957) and Darvocet
20 (in 1973).

21 214. On February 18, 2002, Eli Lilly sold the marketing rights to Darvocet and Darvon to
22 NeoSan, pursuant to an Assignment, Transfer, and Assumption Agreement between the two.

23 215. Eli Lilly generated substantial revenue and other benefits from this sale.

24 216. Upon information and belief, this sale was made possible, at least in part, because of
25 Eli Lilly's false and misleading statements regarding the safety and effectiveness of Propoxyphene
26 Products.

27 217. Upon information and belief, the foregoing misleading statements were made to the
28 FDA, to the public and to the health care community.

1 218. Plaintiff does not yet know the extent and specifics of such statements, as such
2 information is in the control of Defendants, and Plaintiff must engage in discovery to learn of same.

3 219. In connection with this transaction, NeoSan acquired the following from Eli Lilly:

- 4
- 5 a. all rights, title and interest in Eli Lilly's propoxyphene or propoxyphene-based
6 pharmaceutical products (including such products wherein propoxyphene is at
7 least one of the active ingredients) in all forms marketed or marketable in the
8 United States under certain propoxyphene-related product NDAs owned by Eli
9 Lilly;
- 10 b. all propoxyphene-related product NDAs owned by Eli Lilly;
- 11 c. intellectual property related to the transferred propoxyphene-related
12 pharmaceutical products, including (1) Eli Lilly's copyrights, including
13 package inserts, (2) any unique appearance, look, shape, size, or color of the
14 products, and (3) Eli Lilly's trademarks, including those for the names
15 Darvocet-N, Darvon-N, and Darvon.
- 16 d. marketing and promotional materials related to the acquired products;
- 17 e. all books and records related to the purchased products; and
- 18 f. with regard to the acquired products, a license to use all Eli Lilly's experience
19 and other know-how.

20 220. However, Eli Lilly specifically retained a combination patent related to
21 dextropropoxyphene, under patent number 4,594,358, and patent application number 60/188,135,
22 filed March 9, 2000.

23 221. NeoSan, in turn, granted Eli Lilly the following consideration in connection with the
24 transfer of assets:

- 25 a. \$211,400,000, which Eli Lilly amortized over three years;
- 26 b. royalties based on sales of NeoSan's future developed improvements to the
27 Darvon product line or other products containing the active ingredient
28 propoxyphene and any other pharmaceutical products sold under the name
Darvon, Darvocet or other Eli Lilly trademarks, excluding the products
specifically acquired from Eli Lilly;
- c. all licenses necessary for Eli Lilly to fulfill its obligations under a
manufacturing agreement between the parties (described further infra) or
necessary for Eli Lilly to sell the acquired products outside of the United
States;

- d. the right to audit NeoSan as related to its "performance" and royalty payment obligations; and
- e. for products using the trademarks transferred in connection with the agreement, NeoSan was obligated to provide to Eli Lilly free of charge two then-current production samples of each such product (with then-current packaging) not manufactured by Eli Lilly, and (ii) permit Eli Lilly to inspect the manufacturing process for each such product, so long as the products were manufactured by parties other than Eli Lilly.

222. Eli Lilly and the aaiPharma Entities further agreed to the following joint obligations:

- a. to cooperate in any inspection, investigation, or other inquiry from a government agency related to the acquired products, including the right to be present during any such inspection and to make the others party's employees available during such investigation;
- b. to form an implementation team to oversee the activities contemplated by the agreement;
- c. to prepare all necessary government filings;
- d. to agree to and execute a manufacturing agreement;
- e. to enter into a "Quality Agreement," which Plaintiff has not been able to discover through public sources;
- f. to permit audits to monitor compliance with the agreements;
- g. to enter into an agreement whereby aaiPharma guaranteed NeoSan's performance;
- h. to keep confidential all confidential information;
- i. to indemnify each other for losses caused by the indemnifying party's breaches of the agreement; and
- j. to bind all successors and assigns.

223. The Assignment, Transfer, and Assumption Agreement specifically indicates that nothing therein would forbid Eli Lilly from fulfilling the requirements of a 1994 propoxyphene supply agreement that it had with Mylan and/or Mylan Pharmaceuticals.

1 224. In connection with the Assignment, Transfer, and Assumption Agreement, NeoSan
2 and Eli Lilly also entered into a Manufacturing Agreement on February 18, 2002, which was set to
3 expire on December 31, 2004, subject to a six month extension at NeoSan's election.

4 225. Under the Manufacturing Agreement, NeoSan agreed to purchase a set percentage of
5 its Darvocet and Darvon from Eli Lilly, who would manufacture the products, which equaled 60% in
6 the first year of the contract, 50% in the second contract year, and 40% in the third contract year.

7 226. The Manufacturing Agreement also obligated Eli Lilly to transfer its existing
8 inventory of Darvocet and Darvon products to NeoSan, and provided that the aaiPharma Entities
9 would "not re-label or over-label any such Product inventory without the prior written consent of
10 Lilly, which consent will not be unreasonably withheld."

11 227. The publicly available Manufacturing Agreement Plaintiff has been able to discover
12 did not include multiple exhibits and related documents to that agreement, including but not limited
13 to a Quality Agreement setting forth certain quality and regulatory responsibilities relating to the
14 manufacture and release for sale of the Product by Eli Lilly to NeoSan, a schedule setting forth the
15 specifications for manufacturing and packaging the product, a schedule setting forth the amount of
16 inventory transferred from Eli Lilly to the aaiPharma Entities and the prices paid for that product, and
17 a Manufacturing Responsibility Document setting forth additional written instructions regarding the
18 manufacture and sale of the products.

19 228. In addition to NeoSan's agreement with Eli Lilly, aaiPharma LLC entered into a
20 Manufacturing and Supply Agreement with DSM Pharmaceuticals, Inc. ("DSM") on January 26,
21 2004, which specified that DSM would exclusively manufacture and supply Darvocet-N 100 for
22 aaiPharma LLC for five years from the first commercial production of the product.

23 229. The agreement also stated that DSM would be responsible for distributing any product
24 that had already been manufactured by aaiPharma LLC or any third party. Upon information and
25 belief, these "third parties" included Eli Lilly and the products in question included at least the
26 Darvocet-N 100 acquired by the aaiPharma Entities from Eli Lilly.

27
28 **B. The aaiPharma Entities Were Investigated for Securities Fraud and Filed
for Bankruptcy.**

1 230. After NeoSan acquired the marketing rights to Darvocet and Darvon, the aaiPharma
2 Entities reported high sales for those products in their public filings with the Securities and Exchange
3 Commission ("SEC").

4 231. Certain analysts questioned the public numbers, noting that industry data on written
5 prescriptions did not reflect increased demand for either Darvocet or Darvon and suggesting that the
6 aaiPharma Entities had been engaging in "channel stuffing" for both products, i.e. counting shipped-
7 but-unsold drugs as revenue, even though some of them likely would be returned.

8 232. In 2003, the aaiPharma Entities received a letter from the SEC generally addressing
9 the same issue.

10 233. These issues came to a head in 2004, when the aaiPharma Entities announced an
11 internal investigation and disclosed that they had received five subpoenas from a grand jury in
12 Charlotte, North Carolina seeking information about the sales of Darvocet and Darvon.

13 234. Ultimately, the aaiPharma Entities disclosed that they had overstated their revenue by
14 counting shipped-but-not sold product (specifically including Darvocet and Darvon) as revenue, and
15 in the wake of this revelation, the company filed for Chapter 11 bankruptcy on May 9, 2005.

16 235. As a result of these events, the aaiPharma Entities' former CEO – David M. Hurley –
17 pled guilty to fraud and financial misrepresentation, and settled civil charges with the SEC.

18 **C. Xanodyne acquired the NDAs for Darvocet and Darvon and assumed the**
19 **aaiPharma Entities' obligations to Eli Lilly**

20 236. On July 25, 2005, the aaiPharma Entities (which were then in the process of
21 bankruptcy proceedings) sold their drug business (including the propoxyphene products) to
22 Xanodyne.

23 237. Specific assets sold included the following:

- 24
- 25 a. NDAs related to propoxyphene products, including NDA 10-996 (Darvon
26 Compound, Darvon Compound-65 and Darvon with ASA), NDA 10-997
27 (Darvon 65mg capsules), NDA 16-862 (Darvon N (100 mg tablet)), NDA 17-
28 122 (Darvocet N 50 and Darvocet N 100), NDA 17-507 (Darvocet N
Suspension), and NDA 76-429 (Darvocet A500).
- b. drug manufacturing and investigative files related to propoxyphene products;

- c. all of the aaiPharma Entities' existing inventory of propoxyphene products and propoxyphene bulk active ingredient;
- d. certain intellectual property related to propoxyphene products; and
- e. all of the aaiPharma Entities' rights under certain contracts, specifically including the aaiPharma Entities' rights under the 2002 Assignment, Transfer, and Assumption Agreement between NeoSan and Eli Lilly.

238. Xanodyne accordingly assumed NeoSan's obligation to pay Eli Lilly royalties for product reformulations, i.e. the royalty obligation created by the 2002 Assignment, Transfer, and Assumption Agreement.

239. Xanodyne also assumed all other obligations of NeoSan under the 2002 Assignment, Transfer, and Assumption Agreement.

240. The bankruptcy Court authorized assignment of NeoSan's obligations under the 2002 Assignment, Transfer, and Assumption agreement to Xanodyne in an order dated July 18, 2005. Bkruptcy. Ct. Del. 05-11341-CSS, Dckt. # 296.

241. The purchase and sale agreement between the aaiPharma Entities and Xanodyne explicitly noted that the aaiPharma Entities were in default on payment obligations for raw propoxyphene purchased from Eli Lilly.

242. In conjunction with the purchase and sale agreement, Xanodyne entered into a "Master Services Agreement" with AAI DS.

243. Under that agreement, Xanodyne agreed that AAI DS would manufacture 100% of Xanodyne's Darvocet-N 50, Darvon, Darvon-N, and Darvon Compound 65.

244. This agreement continued until 2009, when the aaiPharma Entities sold their contract manufacturing assets to AAI Services, a newly created company. AAI Services appears to have manufactured propoxyphene products for Xanodyne until those products were removed from the market.

245. Darvocet A500, one of the Propoxyphene Products sold to Xanodyne by the aaiPharma Entities, was purchased by the aaiPharma Entities from Athlon Pharmaceuticals Inc. ("Athlon") in July 2003. Under the terms of the agreement, the aaiPharma Entities owe Athlon

1 royalties in an amount equal to 10% of the net sales of Darvocet A500 and any other combination
2 propoxyphene napsylate and acetaminophen products that they may sell in the future through 2023.

3 246. Darvocet A500 was manufactured and supplied by Mikart, Inc. and was to be supplied
4 by Mikart, Inc. until 2013, but in June 2004, the aaiPharma Entities notified Athlon that Athlon had
5 breached a related services agreement, and initiated litigation. Athlon brought counterclaims seeking
6 payment of unpaid monthly payments under the contract and additional litigation with respect to the
7 royalty provisions in the asset purchase agreement. Despite Plaintiff's best efforts, it remains unclear
8 whether these royalty payments are still owed to Athlon by Xanodyne as the aaiPharma Entities'
9 successor-in-interest.

10 247. On February 21, 2007 Xanodyne and DSM entered into an agreement for the
11 manufacture of Darvocet. Upon information and belief, DSM continued to produce Darvocet-N 100
12 for Xanodyne pursuant to its prior agreement with the aaiPharma Entities, and entered into a separate
13 agreement with Xanodyne to continue manufacturing the same. Therefore, DSM had separate
14 contractual agreements with both the aaiPharma Entities and Xanodyne to manufacture Darvocet.

15 **D. Both the aaiPharma Entities and Xanodyne sold Darvocet and Darvon**
16 **labeled by Eli Lilly.**

17
18 248. Because of the aaiPharma Entities' bankruptcy, the Delaware bankruptcy court had to
19 approve the asset sale.

20 249. In connection with that sale, Eli Lilly filed documents indicating the aaiPharma
21 Entities was responsible for paying Medicare/Medicaid reimbursements for all Darvon or Darvocet
22 products sold after the effective date of the 2002 Assignment, Transfer and Assumption Agreement.

23 250. As described above, the aaiPharma Entities acquired Eli Lilly's inventory of Darvon
24 and Darvocet products when the 2002 Assignment, Transfer and Assumption Agreement was
25 executed. Eli Lilly's filings in the bankruptcy court indicate that this was "product manufactured and
26 labeled by Lilly."

27 251. Individual state Medicaid agencies would invoice Eli Lilly for Medicare or Medicaid
28 reimbursements in connection with sale of the acquired inventory, i.e., Eli Lilly would be charged

1 when NeoSan sold Darvocet or Darvon drawn from Eli Lilly's pre-agreement inventory. Eli Lilly
2 would in turn invoice NeoSan/the aaiPharma Entities for these charges.

3 252. As of July 6, 2005, Eli Lilly contended the aaiPharma Entities owed Eli Lilly
4 \$1,093,931.78 in such charges. Eli Lilly indicated it expected further amounts would accrue between
5 January 1, 2005 and the effective date of Xanodyne's assumption of the 2002 Agreement, and that it
6 was likely that additional amounts would accrue even after Xanodyne assumed the contract, although
7 Plaintiff requires discovery to determine the extent and amount of these payments.

8 253. This indicates that the aaiPharma Entities likely sold Eli Lilly-labeled product even
9 after buying the NDA, and that Xanodyne may have sold the same, although Plaintiff will require
10 discovery to determine the extent and amount of such sales.

11 254. Statements made by Xanodyne in public filings confirm this. In a Form S-1 filed with
12 the Securities and Exchange Commission on June 8, 2008, Xanodyne noted that:

13
14 The products that we acquired from AAIPharma in July 2005 had been
15 previously acquired by AAIPharma from various other third parties. Before
16 selling these products to us, AAIPharma continued to use the third parties'
17 National Drug Code, or NDC, numbers for the products. Among other
18 purposes, state Medicare and Medicaid programs use NDC numbers to track
19 product utilization. Because AAIPharma used the third parties' NDC
20 numbers, these third parties paid the Medicaid and Medicare rebates directly
21 and billed AAIPharma in arrears. At the time of acquisition and for a period
22 of time following the acquisition, this created an unpredictable rebate history
23 for these products on which to base our Medicaid and Medicare rebate
24 accruals.

25 255. Upon information and belief, these "third parties" included Eli Lilly and the products
26 in question included the Propoxyphene Products acquired by the aaiPharma Entities from Eli Lilly.

27 256. Xanodyne went on to indicate that they were able to pay the referred-to Medicare
28 rebates directly "after transitioning the NDC numbers for the products to Xanodyne NDC numbers."

29 257. Xanodyne's Form S-1 also noted that Xanodyne believed the trademarks on Darvocet
30 and Darvon were "an important factor in marketing those products," and that it relied on "brand
31 reputation and awareness among physicians and patients to generate ongoing market demand for and
32 sale of" Darvocet and Darvon without promotional efforts from Xanodyne.

E. Xanodyne was Obligated to Pay Royalties to Eli Lilly for Its Sales of Darvocet.

258. Xanodyne's 2008 Form In S-1 Registration Statement contained the following assertion:

As a result of our acquisition of all of AAIPharma's rights to Darvon and Darvocet, including the related trademarks and NDAs that AAIPharma had originally acquired from Eli Lilly in February 2002, we have agreed to pay Eli Lilly a royalty based on net sales in the United States above specified sales thresholds of all forms of Darvon and Darvocet covered by the acquired NDAs and, with specified exceptions, any new pharmaceutical product containing the active pharmaceutical ingredient propoxyphene or the name "Darvon" or "Darvocet." We do not currently expect to pay this royalty prior to FDA approval and the initiation of commercial sale of XP20B, which we expect to market as a line extension of our Darvocet brand. We do not anticipate this to occur earlier than 2011.

259. That same form contained the following statement:

We have agreed to pay AAIPharma a royalty through December 2011 based on quarterly net sales of Zipsor, XP20B and any orally administered follow on products. If we decide to develop any pain products containing the active pharmaceutical ingredient propoxyphene or diclofenac, or opioid products in combination with acetaminophen or an NSAID, or if we elect to continue to develop any pain products offered to us by AAIPharma, we are obligated to pay AAIPharma a royalty based on net sales of such pain products for ten years following commercial launch.

260. XP20B was a time-release combination propoxyphene and acetaminophen modified release oral tablet being developed by Xanodyne.

F. Xanodyne Relied on Third Parties to Manufacture and Perform Other Services Related to Its Product Line of Propoxyphene Products.

261. Xanodyne has stated in its S-1/A filing of January 11, 2008 that it does not own or operate, and has no plans to establish, any manufacturing facilities for its products, which would include Darvocet and other branded propoxyphene products.

1 262. Xanodyne further stated in this filing that it relies, and continues to rely, upon third
 2 parties for the supply of the active pharmaceutical ingredients in its products, which would include
 3 Darvocet and other branded propoxyphene products.

4 263. Xanodyne further stated in this filing that it has entered into manufacturing
 5 agreements with various entities, including but not limited to, the aaiPharma Entities.

6 264. Xanodyne further stated in this filing that it relies on third parties, such as the
 7 aaiPharma Entities, to conduct clinical trials of propoxyphene-containing medications.

8 265. As discovery is on-going, Plaintiff is still in the process of discovering the extent of
 9 the various relationships by and among Xanodyne and other Defendants in this case, except to the
 10 extent set forth elsewhere in this Complaint.

11 **G. The Innovator and Brand Defendants Were Inter-Related.**

12 266. Even after selling the intellectual property rights associated with propoxyphene-
 13 containing drugs such as Darvocet and Darvon, the Innovator and Brand Defendants retained
 14 significant rights and control with respect to the manufacturing, labeling, and distribution of the drugs
 15 and continued to reap royalties based on net sales of the drugs in the United States, and as a result,
 16 they had an ongoing interest in maintaining sales of Propoxyphene Products such as Darvocet and
 17 Darvon.

18 267. In particular, the Assignment, Transfer, and Assumption Agreement between Eli Lilly
 19 and NeoSan referenced above, required Eli Lilly to share its experience and other know-how related
 20 to Propoxyphene Products such as Darvocet and Darvon with NeoSan.

21 268. As a result of the foregoing, the Innovator and Brand Defendants are liable to Plaintiff,
 22 jointly and severally, due to the foregoing contractual and other relationships by, between and among
 23 the Innovator and Brand Name Defendants, at all relevant times, under the legal doctrine(s) of
 24 agency, vicarious liability, and/or respondeat superior.

25
 26 **IV. NDC NUMBERS AND PLAINTIFFS' INGESTION OF PROPOXYPHENE**
 27 **PRODUCTS**
 28

1 269. Upon information and belief, as alleged above, Plaintiffs ingested propoxyphene
2 containing prescription drugs manufactured by Defendants.

3 270. Ingestion of a prescription drug may be demonstrated by various means. One such
4 method is through the use of a National Drug Code ("NDC") identifier.

5 271. The NDC number may be, but is not always, helpful in identifying the particular
6 medication taken by a particular patient.

7 272. For instance, 21 CFR 201.2 states that "[t]he National Drug Code (NDC) number is
8 requested but not required to appear on all drug labels and in all drug labeling, including the label of
9 any prescription drug container furnished to a consumer."

10 273. At other times, the pharmacy or other entity dispensing the medication may no longer
11 possess the documents that would provide an otherwise valid NDC number, or some pharmacies do
12 not include NDC numbers in their records.

13 274. In other instances, it can take six months or longer to obtain records, even from
14 established retail pharmacies. Other, unique problems can arise in obtaining such records for a
15 plaintiff who obtained his or her prescription by mail.

16 275. Additionally, in a preamble to the NDC directory, the FDA states, among other things,
17 that "The NDC Directory contains ONLY information submitted to FDA in SPL electronic listing
18 files by labelers. (A labeler may be either a manufacturer, including a repackager or relabeler, or, for
19 drugs subject to private labeling arrangements, the entity under whose own label or trade name the
20 product will be distributed.)."

21 276. In sum, the NDC number is not always available, and there are other methods to
22 establish proof of ingestion of a particular Propoxyphene Product.

23
24 **FIRST CAUSE OF ACTION**
25 **STRICT PRODUCTS LIABILITY – DESIGN DEFECT**
 (Against All Defendants)

26 277. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
27 Complaint.
28

1 278. At all relevant times, the Innovator and Brand Defendants were engaged in the
2 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
3 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
4 Propoxyphene Products.

5 279. At all relevant times, the Generic Defendants were engaged in the business of
6 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
7 supplying, marketing and/or promoting generic Propoxyphene Products.

8 280. At all relevant times, all Propoxyphene Products were associated with a greatly
9 increased risk of developing severe adverse cardiovascular effects that could result in death, and that
10 risk outweighed their benefit for pain relief.

11 281. At all relevant times, practical and medically-feasible alternate pain management
12 medications that did not contain propoxyphene or involve an increased risk of serious adverse
13 cardiovascular effects that could result in death were available.

14 282. At all relevant times, the risks associated with Propoxyphene Products, and the ability
15 to avoid them by using other available, practical and medically-feasible pain management
16 medications, were beyond that which would be contemplated by the ordinary physician who
17 prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene
18 Products.

19 283. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
20 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
21 alternate pain management medications.

22 284. For these reasons, at all relevant times, all of Defendants' Propoxyphene Products
23 were in an unreasonably dangerous and defective condition.

24 285. For these reasons, all of Defendants' Propoxyphene Products that Plaintiffs purchased
25 and ingested were in an unreasonably dangerous and defective condition at the time of purchase.

26 286. All of Defendants' Propoxyphene Products that Plaintiffs purchased and ingested was
27 expected to and did reach Plaintiffs without substantial change in the unreasonably dangerous and in
28 a defective condition in which they were when they left the hands of Defendants.

288. At all relevant times herein, Defendants had full knowledge of the true cardiac risks associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to withdraw these products from the market or to stop selling the products.

289. As a direct and proximate result of the defective and inappropriate design and the unreasonably dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to comply with federal standards and requirements, the Plaintiffs suffered severe and permanent injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

290. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against All Defendants)

291. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

292. At all relevant times, the Innovator and Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging,

1 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
2 Propoxyphene Products.

3 293. At all relevant times, the Generic Defendants were engaged in the business of
4 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
5 supplying, marketing and/or promoting generic Propoxyphene Products.

6 294. At all relevant times:

- 7 a. propoxyphene had not been adequately tested;
- 8 b. Propoxyphene Products were associated with a greatly increased risk of serious
9 adverse cardiovascular events that could result in death, which outweighed
10 their benefit for pain relief;
- 11 c. the risks, and the nature, scope, severity and duration of any serious side
12 effects, were greater with Propoxyphene Products than with other practical,
13 medically feasible and available pain management medications;
- 14 d. Propoxyphene Products were unreasonably dangerous to the health of patients
15 suffering from pain; and
- 16 e. Propoxyphene Products were no more effective for pain management than
17 other available, practical, and medically-feasible alternate pain management
18 medications, such as over-the-counter acetaminophen (brand name Tylenol),
19 which posed less risk.

20 295. At all relevant times, the risks associated with Propoxyphene Products, and the ability
21 to avoid them by using other available, practical and medically-feasible pain management
22 medications, were beyond that which would be contemplated by the ordinary physician who
23 prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene
24 Products.

25 296. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
26 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
27 alternate pain management medications.

28 297. At all relevant times, Defendants failed to adequately warn the general public or the
medical community – including Plaintiffs and their treating physicians – about any of the risks
outlined above, or about the availability of practical and medically-feasible alternatives.

1 298. More specifically, Defendants failed to adequately warn the general public or the
2 medical community – including Plaintiffs and their treating physicians – that:

- 3 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
4 was not significantly superior to placebo in managing pain, acetaminophen
5 alone was;
- 6 b. In 1978, the Health Research Group filed a petition with the FDA requesting
7 the recall of Darvon based on its claim that it was a dangerous drug of
8 questionable effectiveness, and subsequently submitted studies supporting that
9 propoxyphene could be toxic to the cardiovascular system;
- 10 c. In January 2005, health officials in Great Britain called for a phased
11 withdrawal of propoxyphene-containing products because they were concerned
12 about the cardiac effects associated with their use and were unable to identify
13 any patient group in whom the risk benefit ratio may be positive;
- 14 d. In June 2009, the European Medicines Agency recommended withdrawal
15 across the European Union of marketing authorizations for propoxyphene-
16 containing medications because available evidence suggested that
17 acetaminophen alone was as effective as an acetaminophen-propoxyphene
18 combination, and that the benefits of medicines containing propoxyphene,
19 either alone or in combination, did not outweigh their risks.
- 20 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
21 concerning the risk of fatal overdose, and to add warnings to its label about
22 propoxyphene's dangers overall, for elderly patients, and in terms of its
23 potential for abuse and dependence.
- 24 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
25 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
26 MedGuide to highlight important safeguards for use of the drug, and to issue a
27 Public Health Advisory to underscore safety issues.
- 28 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
significant changes to the heart, even when taken at recommended doses.

299. Upon information and belief, the Innovator and Brand Defendants did not comply with
the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

300. Upon information and belief, the Innovator and Brand Defendants also did not timely
implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the
information in the PDR, or communicate the information to prescribing physicians in Dear Health
Care Professional letters or by other means.

1 301. The FDA mandate likewise effectively required the Generic Defendants to issue the
2 Black Box warning and label changes, but upon information and belief, the Generic Defendants
3 likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene
4 Products, or publish the information in the PDR, or communicate the information to prescribing
5 physicians in Dear Health Care Professional letters or by other means.

6 302. It would have been technologically feasible, and would not have been cost-prohibitive,
7 for Defendants to include adequate warnings and instructions in their marketing and labeling
8 materials, and in their communications to the general public and the health care community.

9 303. Defendants instead used their resources to downplay the risks associated with
10 propoxyphene and Propoxyphene Products in their instructional materials, labeling for, and
11 communications about Propoxyphene Products, which was especially misleading given their past and
12 continued efforts to promote the safety and effectiveness of the drugs.

13 304. At all relevant times, all of Defendants' Propoxyphene Products were in an
14 unreasonably dangerous and defective condition, because they were distributed without the warnings
15 outlined above.

16 305. For these reasons, all of Defendants' Propoxyphene Products that Plaintiffs purchased
17 and ingested were in an unreasonably dangerous and defective condition at the time of purchase.

18 306. All of Defendants' Propoxyphene Products that Plaintiffs purchased and ingested were
19 expected to and did reach Plaintiffs without substantial change in the unreasonably dangerous and
20 defective condition in which they were when they left the hands of Defendants.

21 307. Plaintiffs took their Propoxyphene Products in the intended and prescribed manner,
22 and as a direct and proximate result, suffered the injuries described above.

23 308. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
24 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
25 withdraw these products from the market or to stop selling the products.

26 309. As a direct and proximate result of the defective and inappropriate warnings and the
27 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
28 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as

1 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
 2 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
 3 lost wages and earnings, and were otherwise physically, emotionally, and economically
 4 injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from
 5 the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
 6 continue into the future.

7 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 8 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
 9 the Court deems proper.

10 **THIRD CAUSE OF ACTION**
 11 **STRICT LIABILITY IN TORT**
 12 **(Against All Defendants)**

13 310. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 14 Complaint.

15 311. Defendants used and controlled toxic propoxyphene for use in humans.

16 312. Propoxyphene is highly toxic, inherently dangerous, and ultra-hazardous to humans.

17 313. Defendants allowed and directed that toxic propoxyphene be used and directed in
 18 humans.

19 314. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
 20 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
 21 withdraw these products from the market or to stop selling the products.

22 315. As a direct and proximate result of the defective and inappropriate warnings and the
 23 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
 24 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
 25 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
 26 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
 27 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
 28 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the

1 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
2 continue into the future.

3 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
4 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
5 the Court deems proper.

6 **FOURTH CAUSE OF ACTION**
7 **NEGLIGENT DESIGN**
8 **(Against All Defendants)**

9 316. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
10 Complaint.

11 317. At all relevant times, the Innovator and Brand Defendants were engaged in the
12 business of designing Darvocet/Darvon, brand-name Propoxyphene Products.

13 318. At all relevant times, the Generic Defendants were engaged in the business of
14 designing generic Propoxyphene Products.

15 319. At all relevant times, Defendants had a duty to exercise reasonable care to carefully
16 and properly design their Propoxyphene Products to be reasonably safe prescription pain
17 management medications.

18 320. Defendants breached that duty because all of the Propoxyphene Products that they
19 designed were in an unreasonably dangerous and defective condition, for the reasons described
20 above.

21 321. Because of Defendants' failure to properly design their Propoxyphene Products, those
22 products were placed on the market and sold to Plaintiffs while they were in an unreasonably
23 dangerous and defective condition.

24 322. Plaintiffs purchased and ingested Defendants' Propoxyphene Products, which were in
25 an unreasonably dangerous and defective condition at the time of purchase, in a reasonably
26 foreseeable manner and substantially as intended by Defendants.

27 323. As a direct and proximate result, Plaintiffs suffered the injuries described above.
28

1 324. It was foreseeable that persons like Plaintiffs who ingested Defendants' Propoxyphene
2 Products would, as a direct and proximate result, suffer those injuries.

3 325. In light of what they knew or should have known, Defendants should have anticipated
4 that these injuries were a likely result of the actions and failures to act described above.

5 326. Through these actions and inactions, Defendants knowingly risked the lives of
6 unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and
7 outrageous, and warrants an award of punitive damages.

8 327. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
9 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
10 withdraw these products from the market or to stop selling the products.

11 328. As a direct and proximate result of the negligent design and the unreasonably
12 dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with
13 federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein
14 alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
15 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
16 and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs
17 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
18 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
19 future.

20 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
21 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
22 the Court deems proper.

23 **FIFTH CAUSE OF ACTION**
24 **NEGLIGENCE**
25 **(Against All Defendants)**

26 329. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
27 Complaint.
28

1 330. At all relevant times, the Innovator and Brand Defendants were engaged in the
2 business of researching, testing, studying, distributing, selling, supplying, marketing and/or
3 promoting Darvocet/Darvon, brand-name Propoxyphene Products.

4 331. At all relevant times, the Generic Defendants were engaged in the business of
5 researching, testing, studying, distributing, selling, supplying, marketing and/or promoting generic
6 Propoxyphene Products.

7 332. At all relevant times, Defendants had a duty to:

- 8
- 9 a. exercise reasonable care to conduct adequate studies, tests, surveillance and
10 analyses to assess the risks and adverse effects associated with their
11 Propoxyphene Products; and
12 b. stop distributing, selling and/or supplying them if they discovered that the
13 drugs were unreasonably dangerous and defective.

14 333. Defendants breached those duties, because:

- 15 a. they failed to timely conduct adequate studies, tests, surveillance and analysis,
16 which would have confirmed that their Propoxyphene Products were
17 unreasonably dangerous and defective, for the reasons described above, and
18 that other practical, medically-feasible and safer alternatives were available;
19 and
20 b. they failed to timely stop distributing, selling and/or supplying their
21 Propoxyphene Products once they discovered or should have discovered that
22 those drugs were unreasonably dangerous and defective, and that other
23 practical and medically-feasible alternatives that were safer were available.

24 334. If Defendants had not breached those duties, their unreasonably dangerous and
25 defective Propoxyphene Products would not have been on the market for Plaintiffs to purchase and
26 ingest, and Plaintiffs would not have suffered the injuries described above.

27 335. Because of these breaches, however, Defendants' unreasonably dangerous and
28 defective Propoxyphene Products were on the market, and Plaintiffs purchased and ingested them in a
reasonably foreseeable manner and substantially as intended by Defendants.

 336. As a direct and proximate result, Plaintiffs suffered the injuries described above.

1 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
 2 Propoxyphene Products.

3 344. At all relevant times, the Generic Defendants were engaged in the business of
 4 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
 5 supplying, marketing and/or promoting generic Propoxyphene Products.

6 345. The following were the duties of the Innovator and Brand Defendants at all relevant
 7 times, and the duties of the Generic Defendants following implementation of the Food and Drug
 8 Administration Amendments Act of 2007, and possibly before:

- 9
- 10 a. to assess, manage and communicate the risks, dangers and adverse effects
- 11 associated with Propoxyphene Products to the health care community and the
- 12 general public, including Plaintiffs and their prescribing physicians; and
- 13 b. to distribute their Propoxyphene Products with adequate information about the
- 14 appropriate use of the products and their associated risks provided to the
- 15 general public and the health care community, including Plaintiffs and their
- 16 prescribing physicians.

15 346. Before Plaintiffs were injured by ingesting Defendants' Propoxyphene Products,
 16 Defendants knew or should have known that:

- 17
- 18 a. propoxyphene had not been adequately tested;
- 19 b. Propoxyphene Products were associated with a greatly increased risk of serious
- 20 adverse cardiovascular events that could result in death, which outweighed
- 21 their benefit for pain relief;
- 22 c. the risks, and the nature, scope, severity and duration of any serious side
- 23 effects, were greater with Propoxyphene Products than with other practical,
- 24 medically feasible and available pain management medications;
- 25 d. Propoxyphene Products were unreasonably dangerous to the health of patients
- 26 suffering from pain; and
- 27 e. Propoxyphene Products were no more effective for pain management than
- 28 other available, practical, and medically-feasible alternate pain management
- medications, such as over-the-counter acetaminophen (brand name Tylenol),
- which posed less risk.

1 347. At all relevant times, Defendants knew or should have known that the risks associated
2 with Propoxyphene Products, and the ability to avoid them by using other available, practical and
3 medically-feasible pain management medications, were beyond that which would be contemplated by
4 the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who
5 purchased Propoxyphene Products.

6 348. More specifically, Defendants knew or should have known that the general public and
7 the health care community – including Plaintiffs and their prescribing physicians – would not have
8 been aware of the information outlined above, absent disclosures from Defendants, because:

- 9
- 10 a. the general public and the health care community did not have access to the
 - 11 same resources, analysis and knowledge as Defendants; and
 - 12 b. Defendants manufactured, sold and distributed Propoxyphene Products, and
 - 13 would therefore be assumed to have superior knowledge about them.

14 349. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
15 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
16 alternate pain management medications.

17 350. At all relevant times, Defendants failed to adequately disclose to the general public or
18 the medical community – including Plaintiffs and their treating physicians – about any of the risks
19 outlined above, or about the availability of practical and medically-feasible alternatives.

20 351. More specifically, Defendants failed to adequately disclose to the general public or the
21 medical community – including Plaintiffs and their treating physicians, about the following facts that
22 it knew or should have known:

- 23 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
24 was not significantly superior to placebo in managing pain, acetaminophen
25 alone was;
- 26 b. In 1978, the Health Research Group filed a petition with the FDA requesting
27 the recall of Darvon based on its claim that it was a dangerous drug of
28 questionable effectiveness, and subsequently submitted studies supporting that
 propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased
 withdrawal of propoxyphene-containing products because they were concerned

1 about the cardiac effects associated with their use and were unable to identify
2 any patient group in whom the risk benefit ratio may be positive;

- 3 d. In June 2009, the European Medicines Agency recommended withdrawal
4 across the European Union of marketing authorizations for propoxyphene-
5 containing medications because available evidence suggested that
6 acetaminophen alone was as effective as an acetaminophen-propoxyphene
7 combination, and that the benefits of medicines containing propoxyphene,
8 either alone or in combination, did not outweigh their risks.
- 9 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
10 concerning the risk of fatal overdose, and to add warnings to its label about
11 propoxyphene's dangers overall, for elderly patients, and in terms of its
12 potential for abuse and dependence.
- 13 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
14 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
15 MedGuide to highlight important safeguards for use of the drug, and to issue a
16 Public Health Advisory to underscore safety issues.
- 17 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
18 significant changes to the heart, even when taken at recommended doses.

19 352. Upon information and belief, the Innovator and Brand Defendants did not comply with
20 the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory. The failure to take
21 these actions resulted in inadequate labeling of all Propoxyphene based pharmaceuticals.

22 353. Upon information and belief, the Innovator and Brand Defendants also did not timely
23 implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the
24 information in the PDR, or communicate the information to prescribing physicians in Dear Health
25 Care Professional letters or by other means. The failure to take these actions resulted in inadequate
26 labeling of all Propoxyphene based pharmaceuticals.

27 354. The FDA mandate likewise effectively required the Generic Defendants to issue the
28 Black Box warning and label changes, but upon information and belief, the Generic Defendants
likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene
Products, or publish the information in the PDR, or communicate the information to prescribing
physicians in Dear Health Care Professional letters or by other means.

1 355. It would have been technologically feasible, and would not have been cost-prohibitive,
2 for Defendants to include adequate disclosures in their marketing and labeling materials, and in their
3 communications to the general public and the health care community.

4 356. Defendants instead used their resources to downplay the risks associated with
5 propoxyphene and Propoxyphene Products in their instructional materials, labeling for, and
6 communications about Propoxyphene Products, which was especially misleading given their past and
7 continued efforts to promote the safety and effectiveness of the drugs.

8 357. Plaintiffs and their prescribing physicians justifiably relied on the lack of information
9 about the risks associated with Propoxyphene Products and/or about other available, practical and
10 medically-feasible pain management medications, and acted upon it, by Plaintiffs' physicians
11 prescribing Propoxyphene Products, and Plaintiffs purchasing and ingesting Defendants'
12 Propoxyphene Products.

13 358. Had Defendants provided adequate disclosures:

- 14
- 15 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
16 would have instead prescribed another pain management medication that
17 neither contained propoxyphene nor involved an increased risk of serious
18 adverse cardiovascular events that could result in death, or recommended that
19 Plaintiffs instead take over-the-counter acetaminophen;
- 20 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
21 Products; and
- 22 c. Plaintiffs would not have suffered the injuries described above.

23 359. In light of what Defendants knew or should have known, they should have anticipated
24 that their failure to disclose the dangers of propoxyphene and Propoxyphene Products, and of the
25 availability of practical and medically-feasible alternate pain management medications that posed less
26 risk, would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing
27 and ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious
28 adverse cardiovascular effects that could result in death.

1 360. Plaintiffs prescription for and purchase and ingestion of Defendants' Propoxyphene
2 Products, and the injuries described above that followed, were the direct and proximate result of
3 Defendants' failure to disclose.

4 361. By failing to provide adequate disclosures, Defendants knowingly risked the lives of
5 unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and
6 outrageous, and warrants an award of punitive damages.

7 362. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
8 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
9 withdraw these products from the market or to stop selling the products.

10 363. As a direct and proximate result of the defective and inappropriate warnings and the
11 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
12 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
13 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
14 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
15 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
16 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
17 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
18 continue into the future.

19 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
20 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
21 the Court deems proper.

22 **SEVENTH CAUSE OF ACTION**
23 **FRAUDULENT NONDISCLOSURE**
 (Against All Defendants)

24 364. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
25 Complaint.

26 365. At all relevant times, the Innovator and Brand Defendants were engaged in the
27 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
28

1 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
2 Propoxyphene Products.

3 366. At all relevant times, the Generic Defendants were engaged in the business of
4 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
5 supplying, marketing and/or promoting generic Propoxyphene Products.

6 367. The following were the duties of the Innovator and Brand Defendants at all relevant
7 times, and the duties of the Generic Defendants following implementation of the Food and Drug
8 Administration Amendments Act of 2007, and possibly before:

- 9
- 10 a. to assess, manage and communicate the risks, dangers and adverse effects
11 associated with Propoxyphene Products to the health care community and the
12 general public, including Plaintiffs and their prescribing physicians; and
 - 13 b. to distribute their Propoxyphene Products with adequate information about the
14 appropriate use of the products and their associated risks provided to the
15 general public and the health care community, including Plaintiffs and their
16 prescribing physicians.

17 368. Before Plaintiffs were injured by ingesting Defendants' Propoxyphene Products,
18 Defendants knew that:

- 19
- 20 a. propoxyphene had not been adequately tested;
 - 21 b. Propoxyphene Products were associated with a greatly increased risk of serious
22 adverse cardiovascular events that could result in death, which outweighed
23 their benefit for pain relief;
 - 24 c. the risks, and the nature, scope, severity and duration of any serious side
25 effects, were greater with Propoxyphene Products than with other practical,
26 medically feasible and available pain management medications;
 - 27 d. Propoxyphene Products were unreasonably dangerous to the health of patients
28 suffering from pain; and
 - e. Propoxyphene Products were no more effective for pain management than
other available, practical, and medically-feasible alternate pain management
medications, such as over-the-counter acetaminophen (brand name Tylenol),
which posed less risk.

1 369. At all relevant times, Defendants knew that the risks associated with Propoxyphene
2 Products, and the ability to avoid them by using other available, practical and medically-feasible pain
3 management medications, were beyond that which would be contemplated by the ordinary physician
4 who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene
5 Products.

6 370. More specifically, Defendants knew that the general public and the health care
7 community – including Plaintiffs and their prescribing physicians – would not have been aware of the
8 information outlined above, absent disclosures from Defendants, because:

- 9
- 10 a. the general public and the health care community did not have access to the
 same resources, analysis and knowledge as Defendants; and
 - 11 b. Defendants manufactured, sold and distributed Propoxyphene Products, and
12 would therefore be assumed to have superior knowledge about them.
- 13

14 371. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
15 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
16 alternate pain management medications.

17 372. At all relevant times, Defendants failed to adequately disclose to the general public or
18 the medical community – including Plaintiffs and their treating physicians – about any of the risks
19 outlined above, or about the availability of practical and medically-feasible alternatives.

20 373. More specifically, Defendants failed to adequately disclose to the general public or the
21 medical community – including Plaintiffs and their treating physicians, about the following facts that
22 it knew:

- 23 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
24 was not significantly superior to placebo in managing pain, acetaminophen
 alone was;
- 25 b. In 1978, the Health Research Group filed a petition with the FDA requesting
26 the recall of Darvon based on its claim that it was a dangerous drug of
27 questionable effectiveness, and subsequently submitted studies supporting that
 propoxyphene could be toxic to the cardiovascular system;
- 28 c. In January 2005, health officials in Great Britain called for a phased
 withdrawal of propoxyphene-containing products because they were concerned

1 about the cardiac effects associated with their use and were unable to identify
2 any patient group in whom the risk benefit ratio may be positive;

- 3 d. In June 2009, the European Medicines Agency recommended withdrawal
4 across the European Union of marketing authorizations for propoxyphene-
5 containing medications because available evidence suggested that
6 acetaminophen alone was as effective as an acetaminophen-propoxyphene
7 combination, and that the benefits of medicines containing propoxyphene,
8 either alone or in combination, did not outweigh their risks.
- 9 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
10 concerning the risk of fatal overdose, and to add warnings to its label about
11 propoxyphene's dangers overall, for elderly patients, and in terms of its
12 potential for abuse and dependence.
- 13 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
14 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
15 MedGuide to highlight important safeguards for use of the drug, and to issue a
16 Public Health Advisory to underscore safety issues.
- 17 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
18 significant changes to the heart, even when taken at recommended doses.

19 374. Upon information and belief, the Innovator and Brand Defendants did not comply with
20 the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory. The failure to take
21 these actions resulted in inadequate labeling of all Propoxyphene based pharmaceuticals.

22 375. Upon information and belief, the Innovator and Brand Defendants also did not timely
23 implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the
24 information in the PDR, or communicate the information to prescribing physicians in Dear Health
25 Care Professional letters or by other means. The failure to take these actions resulted in inadequate
26 labeling of all Propoxyphene based pharmaceuticals.

27 376. The FDA mandate likewise effectively required the Generic Defendants to issue the
28 Black Box warning and label changes, but upon information and belief, the Generic Defendants
likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene
Products, or publish the information in the PDR, or communicate the information to prescribing
physicians in Dear Health Care Professional letters or by other means.

1 377. It would have been technologically feasible, and would not have been cost-prohibitive,
2 for the Defendants to include adequate disclosures in their marketing and labeling materials, and in
3 their communications to the general public and the health care community.

4 378. Defendants instead used their resources to conceal and downplay the risks associated
5 with Propoxyphene Products in their promotional materials, instructional materials, labeling for, and
6 communications about Propoxyphene Products, which was especially misleading given their past and
7 continued efforts to promote the safety and effectiveness of the drugs. Defendants failed to disclose
8 the material information outlined above because they wanted the general public and the health care
9 community – including Plaintiffs and their prescribing physicians – to believe that Propoxyphene
10 Products were safe and effective, and wanted to induce medical providers – including Plaintiffs
11 prescribing physicians – to prescribe Propoxyphene Products, and consumers – including Plaintiffs –
12 to purchase and ingest their Propoxyphene Products.

13 379. Plaintiffs and their prescribing physicians justifiably relied on the lack of information
14 about the risks associated with Propoxyphene Products and/or about other available, practical and
15 medically-feasible pain management medications, and acted upon it, by Plaintiffs physicians
16 prescribing Propoxyphene Products, and Plaintiffs purchasing and ingesting Defendants'
17 Propoxyphene Products.

18 380. Had Defendants provided adequate disclosures:

- 19
- 20 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
21 would have instead prescribed another pain management medication that
22 neither contained propoxyphene nor involved an increased risk of serious
23 adverse cardiovascular events that could result in death, or recommended that
24 Plaintiffs instead take over-the-counter acetaminophen;
- 25 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
26 Products; and
- 27 c. Plaintiffs would not have suffered the injuries described above.

28 381. In light of what Defendants knew, they had to have known or anticipated that their
failure to disclose the dangers of propoxyphene and Propoxyphene Products, and of the availability of

1 practical and medically-feasible alternate pain management medications that posed less risk, would
2 likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and
3 ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious
4 adverse cardiovascular effects that could result in death.

5 382. Plaintiffs prescription for and purchase and ingestion of Defendants' Propoxyphene
6 Products, and the injuries described above that followed, were the direct and proximate result of
7 Defendants' knowing failure to disclose.

8 383. By failing to make the disclosures outlined above, Defendants knowingly risked the
9 lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was
10 extreme and outrageous, and warrants an award of punitive damages.

11 384. Upon information and belief, Plaintiffs allege that Defendants actively and
12 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
13 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
14 Plaintiffs, from discovery these hazards.

15 385. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
16 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
17 withdraw these products from the market or to stop selling the products.

18 386. As a direct and proximate result of the defective manufacturing and the unreasonably
19 dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to
20 comply with federal standards and requirements, the Plaintiffs suffered severe and permanent
21 injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
22 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
23 and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiffs
24 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
25 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
26 future.

27 387. Defendants acted willfully or with gross negligence indicating a wanton disregard for
28 the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The

1 aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate
 2 disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs
 3 to punitive damages in an amount appropriate to punish the Defendants and deter them from similar
 4 conduct in the future.

5 388. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
 6 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
 7 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
 8 them from similar conduct in the future.

9 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 10 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
 11 the Court deems proper.

12 **EIGHTH CAUSE OF ACTION**
 13 **NEGLIGENT MISREPRESENTATION**
 14 **(Against All Defendants)**

15 389. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 16 Complaint.

17 390. At all relevant times, the Innovator and Brand Defendants were engaged in the
 18 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
 19 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
 20 Propoxyphene Products.

21 391. At all relevant times, the Generic Defendants were engaged in the business of
 22 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
 23 supplying, marketing and/or promoting generic Propoxyphene Products.

24 392. The following were the duties of the Innovator and Brand Defendants at all relevant
 25 times, and the duties of the Generic Defendants following implementation of the Food and Drug
 26 Administration Amendments Act of 2007, and possibly before:

- 27 a. to assess, manage and communicate the risks, dangers and adverse effects
 28 associated with Propoxyphene Products to the health care community and the
 general public, including Plaintiff and their prescribing physicians; and

- b. to distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiffs and their prescribing physicians.

393. Before Plaintiffs were injured by ingesting Defendants' Propoxyphene Products, Defendants knew or should have known that:

- a. propoxyphene had not been adequately tested;
- b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;
- c. the risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;
- d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and
- e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

394. More specifically, Defendants knew or should have known that:

- a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;
- b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-

1 containing medications because available evidence suggested that
 2 acetaminophen alone was as effective as an acetaminophen-propoxyphene
 3 combination, and that the benefits of medicines containing propoxyphene,
 4 either alone or in combination, did not outweigh their risks.

- 5 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
 6 concerning the risk of fatal overdose, and to add warnings to its label about
 7 propoxyphene's dangers overall, for elderly patients, and in terms of its
 8 potential for abuse and dependence.
- 9 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
 10 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
 11 MedGuide to highlight important safeguards for use of the drug, and to issue a
 12 Public Health Advisory to underscore safety issues.
- 13 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
 14 significant changes to the heart, even when taken at recommended doses.

15 395. Despite what the Innovator and Brand Defendants knew or should have known, upon
 16 information and belief, they represented to the general public and the health care community in
 17 reports, press releases, advertising campaigns, television commercials, print advertisements,
 18 billboards, other commercial media, promotional materials, instructional materials and labeling that:

- 19 a. propoxyphene had been adequately tested;
- 20 b. Propoxyphene Products were safe and effective for pain management; and
- 21 c. Propoxyphene Products were more effective for pain management than other
 22 pain management medications.

23 396. Similarly, despite what the Generic Defendants knew or should have known, upon
 24 information and belief, they represented to the general public and the health care community in their
 25 instructional materials and labeling that:

- 26 a. propoxyphene had been adequately tested;
- 27 b. Propoxyphene Products were safe and effective for pain management; and
- 28 c. Propoxyphene Products were more effective for pain management than other
 pain management medications.

1 397. These representations made by Defendants were false at the time that they were made,
2 and Defendants knew or should have known that they were false.

3 398. Defendants knew or should have known that the general public and the health care
4 community – including Plaintiffs and their prescribing physicians – would not have been aware that
5 their statements about the testing, safety and effectiveness associated with Propoxyphene Products
6 were false, and would have instead justifiably relied on them, because:

- 7
- 8 a. the general public and the health care community did not have access to the
 same resources, analysis and knowledge as Defendants; and
 - 9 b. Defendants manufactured, sold and distributed Propoxyphene Products, and
10 would therefore be assumed to have superior knowledge about them.

11 399. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know
12 that Defendants' misrepresentations were false.

13 400. Because of what Defendants knew or should have known, as described above, they
14 failed to exercise reasonable care or competence in making these misrepresentations.

15 401. Plaintiffs and their prescribing physicians justifiably relied and acted upon
16 Defendants' misrepresentations, by Plaintiffs physicians prescribing Propoxyphene Products, and
17 Plaintiffs purchasing and ingesting Defendants' Propoxyphene Products.

18 402. Had Defendants not made these misrepresentations:

- 19
- 20 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
 would have instead prescribed another pain management medication that
21 neither contained propoxyphene nor involved an increased risk of serious
22 adverse cardiovascular events that could result in death, or recommended that
 Plaintiffs instead take over-the-counter acetaminophen;
 - 23 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
24 Products; and
 - 25 c. Plaintiffs would not have suffered the injuries described above.

26

27 403. In light of what Defendants knew or should have known, they should have anticipated
28 that their misrepresentations would likely result in physicians prescribing Propoxyphene Products,

1 and consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and
 2 proximate result, suffering serious adverse cardiovascular effects that could result in death.

3 404. Plaintiffs prescription for and purchase and ingestion of Propoxyphene Products, and
 4 the injuries described above that followed, were the direct and proximate result of Defendants'
 5 misrepresentations.

6 405. By making the misrepresentations described above, Defendants knowingly risked the
 7 lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was
 8 extreme and outrageous, and warrants an award of punitive damages.

9 406. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
 10 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
 11 withdraw these products from the market or to stop selling the products.

12 407. As a direct and proximate result of the defective and inappropriate warnings and the
 13 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
 14 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
 15 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
 16 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
 17 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
 18 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
 19 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
 20 continue into the future.

21 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 22 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
 23 the Court deems proper.

24
 25 **NINTH CAUSE OF ACTION**
 26 **FRAUDULENT MISREPRESENTATION AND CONCEALMENT**
 27 **(Against All Defendants)**

28 408. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 Complaint.

1 409. At all relevant times, the Innovator and Brand Defendants were engaged in the
2 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
3 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
4 Propoxyphene Products.

5 410. At all relevant times, the Generic Defendants were engaged in the business of
6 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
7 supplying, marketing and/or promoting generic Propoxyphene Products.

8 411. The following were the duties of the Innovator and Brand Defendants at all relevant
9 times, and the duties of the Generic Defendants following implementation of the Food and Drug
10 Administration Amendments Act of 2007, and possibly before:

- 11
- 12 a. to assess, manage and communicate the risks, dangers and adverse effects
13 associated with Propoxyphene Products to the health care community and the
14 general public, including Plaintiffs and their prescribing physicians; and
- 15 b. to distribute their Propoxyphene Products with adequate information about the
16 appropriate use of the products and their associated risks provided to the
17 general public and the health care community, including Plaintiffs and their
18 prescribing physicians.

19 412. Before Plaintiffs was injured by ingesting Defendants' Propoxyphene Products,
20 Defendants knew that:

- 21 a. propoxyphene had not been adequately tested;
- 22 b. Propoxyphene Products were associated with a greatly increased risk of serious
23 adverse cardiovascular events that could result in death, which outweighed
24 their benefit for pain relief;
- 25 c. the risks, and the nature, scope, severity and duration of any serious side
26 effects, were greater with Propoxyphene Products than with other practical,
27 medically feasible and available pain management medications;
- 28 d. Propoxyphene Products were unreasonably dangerous to the health of patients
suffering from pain; and
- e. Propoxyphene Products were no more effective for pain management than
other available, practical, and medically-feasible alternate pain management

1 medications, such as over-the-counter acetaminophen (brand name Tylenol),
2 which posed less risk.

3 413. More specifically, Defendants knew that:

- 4 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
5 was not significantly superior to placebo in managing pain, acetaminophen
6 alone was;
- 7 b. In 1978, the Health Research Group filed a petition with the FDA requesting
8 the recall of Darvon based on its claim that it was a dangerous drug of
9 questionable effectiveness, and subsequently submitted studies supporting that
10 propoxyphene could be toxic to the cardiovascular system;
- 11 c. In January 2005, health officials in Great Britain called for a phased
12 withdrawal of propoxyphene-containing products because they were concerned
13 about the cardiac effects associated with their use and were unable to identify
14 any patient group in whom the risk benefit ratio may be positive;
- 15 d. In June 2009, the European Medicines Agency recommended withdrawal
16 across the European Union of marketing authorizations for propoxyphene-
17 containing medications because available evidence suggested that
18 acetaminophen alone was as effective as an acetaminophen-propoxyphene
19 combination, and that the benefits of medicines containing propoxyphene,
20 either alone or in combination, did not outweigh their risks.
- 21 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
22 concerning the risk of fatal overdose, and to add warnings to its label about
23 propoxyphene's dangers overall, for elderly patients, and in terms of its
24 potential for abuse and dependence.
- 25 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
26 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
27 MedGuide to highlight important safeguards for use of the drug, and to issue a
28 Public Health Advisory to underscore safety issues.
- g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
significant changes to the heart, even when taken at recommended doses.

414. Despite what the Innovator and Brand Defendants knew, upon information and belief,
they falsely represented to the general public and the health care community in reports, press releases,
advertising campaigns, television commercials, print advertisements, billboards, other commercial
media, promotional materials, instructional material and labeling that:

- a. propoxyphene had been adequately tested;
- b. Propoxyphene Products were safe and effective for pain management; and
- c. Propoxyphene Products were more effective for pain management than other pain management medications.

415. Similarly, despite what the Generic Defendants knew, upon information and belief, they falsely represented to the general public and the health care community in their instructional materials and labeling that:

- a. propoxyphene had been adequately tested;
- b. Propoxyphene Products were safe and effective for pain management; and
- c. Propoxyphene Products were more effective for pain management than other pain management medications.

416. These representations were all intentionally false and misleading at the time that they were made, and Defendants knew that they were false and misleading, and willfully, wantonly and recklessly disregarded that they were false.

417. Defendants knew that the general public and the health care community – including Plaintiffs and their prescribing physicians – would not have been aware that their statements about the testing, safety and effectiveness associated with Propoxyphene Products were false, and would have instead justifiably relied on them, because:

- a. the general public and the health care community did not have access to the same resources, analysis and knowledge as Defendants; and
- b. Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

418. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know that Defendants' misrepresentations were false.

419. Defendants made these material misrepresentations because they wanted the general public and the health care community to rely on them, and wanted to induce medical providers –

1 including Plaintiffs prescribing physicians – to prescribe Propoxyphene Products, and consumers –
2 including Plaintiffs – to purchase and ingest their Propoxyphene Products.

3 420. Plaintiffs and their prescribing physicians justifiably relied and acted upon
4 Defendants' misrepresentations, by Plaintiffs physicians prescribing Propoxyphene Products, and
5 Plaintiffs purchasing and ingesting Defendants' Propoxyphene Products.

6 421. Had Defendants not made these misrepresentations:

- 7
- 8 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
9 would have instead prescribed another pain management medication that
10 neither contained propoxyphene nor involved an increased risk of serious
11 adverse cardiovascular events that could result in death, or recommended that
12 Plaintiffs instead take over-the-counter acetaminophen;
- 13 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
14 Products, and
- 15 c. Plaintiffs would not have suffered the injuries described above.

16 422. In light of what Defendants knew, they had to have known that their
17 misrepresentations would likely result in physicians prescribing Propoxyphene Products, and
18 consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and proximate
19 result, suffering serious adverse cardiovascular effects that could result in death.

20 423. Plaintiffs prescription for and purchase and ingestion of Propoxyphene Products, and
21 the injuries described above that followed, were the direct and proximate result of Defendants'
22 knowing misrepresentations.

23 424. By making the misrepresentations described above, Defendants knowingly risked the
24 lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was
25 extreme and outrageous, and warrants an award of punitive damages.

26 425. Upon information and belief, Plaintiffs allege that Defendants actively and
27 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
28 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
Plaintiffs, from discovering these hazards.

428. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

429. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION
NEGLIGENCE PER SE
(Against All Defendants)

1 430. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
2 Complaint.

3 431. At all relevant times, the Innovator and Brand Defendants were engaged in the
4 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
5 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
6 Propoxyphene Products.

7 432. At all relevant times, the Generic Defendants were engaged in the business of
8 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
9 supplying, marketing and/or promoting generic Propoxyphene Products.

10 433. Under the doctrine of negligence per se, otherwise known as statutory negligence, the
11 duty of Defendants to exercise reasonable care included the obligation to conform their products and
12 activities related to those products to safety standards imposed by applicable statutes or regulations.

13 434. At all relevant times, Defendants violated federal standards for the sale of prescription
14 drugs set forth in the Federal Food, Drug and Cosmetic Act, at 21 C.F.R. § 310.303, because their
15 Propoxyphene Products were not safe and effective for their intended use.

16 435. Additionally, there were violations of federal standards for the sale of prescription
17 drugs set forth in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., by the
18 Innovator and Brand Defendants at all relevant times, and by the Generic Defendants following
19 implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before,
20 as follows:

- 21 a. Their Propoxyphene Products were adulterated pursuant to 21 U.S.C. § 351
22 because, among other things, their quality fell below the standard set forth in
23 the official compendium for their Propoxyphene Products and such deviations
24 were not plainly stated in their labels.
- 25 b. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352
26 because, among other things, their labeling was false or misleading.
- 27 c. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352
28 because words, statements or other information required by or under authority
 of that section were not prominently placed thereon with such conspicuousness
 and in such terms as to render them likely to be read and understood by the
 ordinary individual under customary conditions of purchase and use.

- d. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352 because the labeling did not bear adequate directions for use, and/or the labeling did not bear adequate warnings against use where their use may have been dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as were necessary for the protection of users.
- e. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352 because they were dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
- f. Their Propoxyphene Products' labeling was not informative and accurate as required by 21 C.F.R. § 201.56.
- g. Their Propoxyphene Products were misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading.
- h. Their Propoxyphene Products were mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling failed to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.
- i. Their Propoxyphene Products were mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drugs.
- j. Defendants failed to list the adverse reactions that occurred with their Propoxyphene Products and other drugs in the same pharmacologically active and chemically related class, as required by 21 C.F.R. § 201.57.
- k. Defendants violated 21 C.F.R. § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there were or might have been grounds for suspending or withdrawing approval of the application for their Propoxyphene Products to the FDA.

436. Such violations constitute a breach of duty of reasonable care toward Plaintiffs that would subject Defendants to civil liability for personal injuries proximately caused by the violations.

437. As a lawful consumer of Defendants' Propoxyphene Products, Plaintiffs was within the class of persons the statutes and regulations described above was designed to protect, and their injuries were the type of harm they were intended to prevent.

1 438. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
2 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
3 withdraw these products from the market or to stop selling the products.

4 439. As a direct and proximate cause of the violations of these statutes and regulations by
5 Defendants, which therefore constitute negligent per se acts and/or omissions, Plaintiffs suffered the
6 injuries set forth in this Complaint.

7 440. By violating these statutes and regulations, Defendants knowingly risked the lives of
8 unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and
9 outrageous, and warrants an award of punitive damages.

10 441. As a direct and proximate result of the defective and inappropriate warnings and the
11 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
12 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
13 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
14 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
15 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
16 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
17 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
18 continue into the future.

19 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
20 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
21 the Court deems proper.

22
23 **ELEVENTH CAUSE OF ACTION**
24 **BREACH OF EXPRESS WARRANTY**
25 **(Against All Defendants)**

26 442. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
27 Complaint.

28 443. At all relevant times, the Innovator and Brand Defendants were engaged in the
business of selling goods, which were Darvocet/Darvon.

1 444. At all relevant times, the Generic Defendants were engaged in the business of selling
2 goods, which were generic Propoxyphene Products.

3 445. Upon information and belief, at all relevant times, Defendants expressly warranted
4 that:

- 5 a. propoxyphene, such as that contained in their Propoxyphene Products, had
6 been adequately tested;
- 7 b. propoxyphene, such as that contained in their Propoxyphene Products, was
8 safe and effective for pain management; and
- 9 c. Propoxyphene Products, such as their Propoxyphene Products, were more
10 effective for pain management than other pain management medications.

11 446. Upon information and belief, Defendants made these express warranties for the benefit
12 of Plaintiffs.

13 447. These express warranties were relied upon, and were part of the basis of the bargain
14 for, Plaintiffs and their prescribing physicians.

15 448. Defendants' Propoxyphene Products did not conform to these express warranties,
16 because:

- 17 a. Propoxyphene, such as that contained in Defendants' Propoxyphene Products,
18 had not been adequately tested;
- 19 b. Propoxyphene Products, such as Defendants' Propoxyphene Products, were
20 associated with a greatly increased risk of serious adverse cardiovascular
21 events that could result in death, which outweighed their benefit for pain relief;
- 22 c. the risks, and the nature, scope, severity and duration of any serious side
23 effects were greater with Propoxyphene Products, such as Defendants'
24 Propoxyphene Products, than with other practical, medically-feasible and
25 available pain management medications;
- 26 d. Propoxyphene Products, such as Defendants' Propoxyphene Products, were
27 unreasonably dangerous to the health of patients suffering from pain; and
- 28 e. Propoxyphene Products, such as Defendants' Propoxyphene Products, were no
29 more effective for pain management than other practical, medically-feasible
30 and available alternate pain management medications, such as over-the-counter
31 acetaminophen (brand name Tylenol), which posed less risk.

32 449. Had Defendants not made these express warranties:

- a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiffs instead take over-the-counter acetaminophen;
- b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene Products; and
- c. Plaintiffs would not have suffered the injuries described above.

450. Upon information and belief, Defendants did, however, make these express warranties, and as a result, Plaintiffs' physicians prescribed Propoxyphene Products, and Plaintiffs purchased and ingested Defendants' Propoxyphene Products, and suffered the injuries described above.

451. Plaintiffs' injuries that are described above were the direct and proximate result of Defendants' breach of their express warranties.

452. At all relevant times herein, Defendants had full knowledge of the true cardiac risks associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to withdraw these products from the market or to stop selling the products.

453. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TWELFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

454. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

455. At all relevant times, the Innovator and Brand Defendants were engaged in the business of selling goods, which were Darvocet/Darvon and owed a duty to consumers regarding all Propoxyphene Products.

456. At all relevant times, the Generic Defendants were engaged in the business of selling goods, which were generic Propoxyphene Products.

457. Defendants sold their Propoxyphene Products to Plaintiffs.

458. The ordinary purpose for which Propoxyphene Products are used is for safe and effective management of pain.

459. The Propoxyphene Products that Defendants sold to Plaintiffs were not fit for their ordinary purpose of providing safe and effective management of pain because:

- a. Propoxyphene, such as that contained in Defendants' Propoxyphene Products, had not been adequately tested;
- b. Propoxyphene Products, such as Defendants' Propoxyphene Products, were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;
- c. the risks, and the nature, scope, severity and duration of any serious side effects were greater with Propoxyphene Products, such as Defendants' Propoxyphene Products, than with other practical, medically-feasible and available pain management medications;
- d. Propoxyphene Products, such as Defendants' Propoxyphene Products, were unreasonably dangerous to the health of patients suffering from pain; and
- e. Propoxyphene Products, such as Defendants' Propoxyphene Products, were no more effective for pain management than other practical, medically-feasible and available alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

1 460. Plaintiffs' injuries that are described above were the direct and proximate result of the
2 failure of Defendants' Propoxyphene Products to be fit for their ordinary purpose of providing safe
3 and effective management of pain.

4 461. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
5 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
6 withdraw these products from the market or to stop selling the products.

7 462. As a direct and proximate result of the defective and inappropriate warnings and the
8 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
9 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
10 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
11 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
12 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
13 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
14 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
15 continue into the future.

16 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
17 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
18 the Court deems proper.

19
20 **THIRTEENTH CAUSE OF ACTION**
21 **DECEIT BY CONCEALMENT – VIOLATION OF**
22 **CALIFORNIA CIVIL CODE §§ 1709, 1710**
23 **(Against All Defendants)**

24 463. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
25 Complaint.

26 464. The Defendants had actual knowledge based upon studies, published reports, and
27 clinical experience, that products containing propoxyphene created an unreasonable risk of serious
28 bodily injury or should have known such information.

 465. The Defendants intentionally omitted, concealed and suppressed this information from

1 the product labeling, promoting, and advertising of products containing propoxyphene and instead
2 labeled, promoted, and advertised products containing propoxyphene as safe in order to avoid losses
3 and sustain profits in its sale to consumers, as Defendants knew that Plaintiffs' healthcare providers
4 would not have exposed Plaintiffs to products containing propoxyphene had Plaintiffs' healthcare
5 providers known or otherwise been aware of the true facts concerning propoxyphene administration.

6 466. Plaintiffs and Plaintiffs' healthcare providers reasonably relied, to their detriment,
7 upon the Defendants' fraudulent actions and omissions in their representations concerning the risks of
8 propoxyphene in the labeling, advertising, and promoting of said product.

9 467. Plaintiffs and Plaintiffs' healthcare providers reasonably relied upon the Defendants'
10 representations to them that propoxyphene was safe for human consumption and/or use and that the
11 Defendants' labeling, advertising, and promotions fully described all known risks of propoxyphene.

12 468. The Defendants' actions, concealment and omissions as described herein demonstrate
13 a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

14 469. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
15 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
16 withdraw these products from the market or to stop selling the products.

17 470. As a direct and proximate result of the defective and inappropriate warnings and the
18 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
19 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
20 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
21 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
22 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
23 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
24 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
25 continue into the future.

26 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
27 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
28 the Court deems proper.

FOURTEENTH CAUSE OF ACTION
VIOLATION OF BUSINESS AND PROFESSIONS CODE § 17200
(Against All Defendants)

471. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

472. Plaintiffs bring this cause of action pursuant to California Business & Professions Code § 17204, in Plaintiffs' individual capacities, and not on behalf of the general public.

473. California Business & Professions Code § 17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

474. The acts and practices described above were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of California Business & Professions Code § 17200. The acts of untrue and misleading advertising are, by definition, violations of California Business & Professions Code § 17200. This conduct includes, but is not limited to:

- a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that propoxyphene was safe, fit, and effective for human use, knowing that said representations were false, and concealing from Plaintiffs, Plaintiffs' physicians, and the general public that propoxyphene had a serious propensity to cause injuries to users;
- b. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that propoxyphene was safe for human use, even though the Defendants knew this to be false, and even though the Defendants had no reasonable grounds to believe them to be true; and
- c. Purposely downplaying and understating the health hazards and risks associated with propoxyphene.

475. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code § 17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code § 17500.

476. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten gains

1 from the sale of propoxyphene in California, sold in large part as a result of the acts and omissions
2 described herein.

3 477. Because of fraudulent misrepresentations made by Defendants as detailed above, and
4 the inherently unfair practice of committing a fraud against the public by intentionally
5 misrepresenting and concealing material information, the acts of Defendants described herein
6 constitute unfair or fraudulent business practices.

7 478. Plaintiffs, pursuant to California Business & Professions Code § 17203, seek an order
8 of this court compelling the Defendants to provide restitution and injunctive relief calling for
9 Defendants, and each of them, to cease unfair business practices in the future.

10 479. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
11 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
12 withdraw these products from the market or to stop selling the products.

13 480. As a direct and proximate result of the defective and inappropriate warnings and the
14 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
15 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
16 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
17 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
18 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
19 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
20 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
21 continue into the future.

22 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
23 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
24 the Court deems proper.

25
26 **FIFTEENTH CAUSE OF ACTION**
27 **VIOLATION OF BUSINESS AND PROFESSIONS CODE § 17500**
28 **(Against All Defendants)**

1 481. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
2 Complaint.

3 482. Plaintiffs bring this cause of action pursuant to California Business & Professions
4 Code § 17500, in Plaintiffs' individual capacities and not on behalf of the general public.

5 483. California Business & Professions Code § 17500 provides that it is unlawful for any
6 person, firm, corporation or association to dispose of property or perform services, or to induce the
7 public to enter into any obligation relating thereto, through the use of untrue or misleading
8 statements.

9 484. At all times herein alleged Defendants have committed acts of disseminating untrue
10 and misleading statements as defined by California Business & Professions Code § 17500 by
11 engaging in the following acts and practices with intent to induce members of the public, including
12 healthcare professionals, to purchase and use products containing propoxyphene:

- 13 a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that
14 propoxyphene was safe, fit, and effective for human use, knowing that said
15 representations were false, and concealing from Plaintiffs, Plaintiffs'
16 physicians, and the general public that propoxyphene had a serious propensity
17 to cause injuries to users;
- 18 b. Engaging in advertising programs designed to create the image, impression and
19 belief by consumers and physicians that propoxyphene was safe for human
20 use, even though the Defendants knew this to be false, and even though the
21 Defendants had no reasonable grounds to believe them to be true; and
- 22 c. Purposely downplaying and understating the health hazards and risks
23 associated with propoxyphene.

24 485. The foregoing practices constitute false and misleading advertising within the meaning
25 of California Business & Professions Code § 17500.

26 486. As a result of their conduct described above, Defendants have been and will be
27 unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten gains
28 from the sale and prescription of products containing propoxyphene in California, sold in large part
as a result of the acts and omissions described herein.

1 487. Pursuant to California Business & Professions Code § 17535, Plaintiffs seek an order
2 of this court compelling the Defendants to provide restitution and injunctive relief calling for
3 Defendants, and each of them, to cease unfair business practices in the future.

4 488. Plaintiffs seek restitution of the monies collected by Defendants, and each of them,
5 and other injunctive relief to cease such false and misleading advertising in the future.

6 489. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
7 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
8 withdraw these products from the market or to stop selling the products.

9 490. As a direct and proximate result of the defective and inappropriate warnings and the
10 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
11 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
12 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
13 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
14 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
15 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
16 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
17 continue into the future.

18 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
19 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
20 the Court deems proper.

21
22 **SIXTEENTH CAUSE OF ACTION**
23 **VIOLATION OF CIVIL CODE § 1750 ET. SEQ.**
 (Against All Defendants)

24 491. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
25 Complaint.

26 492. Plaintiffs are informed and believe and thereon allege that Defendants, and each of
27 them, by the acts and misconduct alleged herein, violated the Consumers Legal Remedies Act,
28 California Civil Code §§ 1750 et. seq. ("CLRA").

1 493. Plaintiffs hereby seek injunctive relief as appropriate against Defendants, and each of
2 them, for their violations of California Civil Code §§ 1750 et. seq. The CLRA applies to Defendants'
3 actions and conduct described herein because it extends to transactions which are intended to result,
4 or which have resulted, in the sale of goods to consumers.

5 494. Plaintiffs are a "consumer" within the meaning of California Civil Code § 1761(d).

6 495. Defendants have violated, and continue to violate, the CLRA in representing that
7 goods have characteristics and benefits which they do not have in violation of California Civil Code §
8 1770(a)(5).

9 496. At all times herein alleged Defendants have committed acts of disseminating untrue
10 and misleading statements as defined by California Civil Code § 1770 by engaging in the following
11 acts and practices with intent to induce members of the public, including healthcare providers, to
12 purchase and use products containing propoxyphene, but is not limited to:

- 13
- 14 a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that
15 propoxyphene was safe, fit, and effective for human use, knowing that said
16 representations were false, and concealing from Plaintiffs, Plaintiffs'
17 physicians, and the general public that propoxyphene had a serious propensity
18 to cause injuries to users;
- 19 b. Engaging in advertising programs designed to create the image, impression and
20 belief by consumers and physicians that propoxyphene was safe for human
21 use, even though the Defendants knew this to be false, and even though the
22 Defendants had no reasonable grounds to believe them to be true; and
- 23 c. Purposely downplaying and understating the health hazards and risks
24 associated with propoxyphene.

25 497. The foregoing practices constitute false and misleading advertising and representations
26 within the meaning of California Civil Code § 1770.

27 498. Pursuant to California Civil Code § 1780, Plaintiffs seek an order of this court for
28 injunctive relief calling for Defendants, and each of them, to cease such deceptive business practices
in the future.

500. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTEENTH CAUSE OF ACTION
NEGLIGENCE

(Against Innovator and Brand Defendants)

501. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

502. At all relevant times, the Innovator and Brand Defendants were engaged in the business of researching, testing, studying, distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name Propoxyphene Products.

503. At all relevant times, the Innovator and Brand Defendants had a duty to:

- a. exercise reasonable care to conduct adequate studies, tests, surveillance and analyses to assess the risks and adverse effects associated with their Propoxyphene Products; and
- b. stop distributing, selling and/or supplying them if they discovered that the drugs were unreasonably dangerous and defective.

1 504. At all relevant times, the Innovator and Brand Defendants knew or should have known
2 that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe,
3 often rely on the statements made about the brand formulations of a drug, and thus that the physicians
4 who prescribed either brand or generic Propoxyphene Products to their patients were relying on the
5 statements that the Innovator and Brand Defendants made about Darvocet and/or Darvon.

6 505. At all relevant times, the Innovator and Brand Defendants knew or should have known
7 that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic
8 than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely
9 would have instead purchased a generic formulation of Darvocet and/or Darvon.

10 506. Because of this knowledge, the duties of the Innovator and Brand Defendants that are
11 outlined above applied at all relevant times not only to the purchasers of the brand products and their
12 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
13 prescribing physicians, including Plaintiffs and their prescribing physicians.

14 507. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
15 ingestion of generic Propoxyphene Products.

16 508. The Innovator and Brand Defendants breached the duties outlined above, because:

- 17
- 18 a. they failed to timely conduct adequate studies, tests, surveillance and analysis,
19 which would have confirmed that their Propoxyphene Products were
20 unreasonably dangerous and defective, for the reasons described above, and
21 that other practical, medically-feasible and safer alternatives were available;
22 and
23 b. they failed to timely stop distributing, selling and/or supplying their
24 Propoxyphene Products once they discovered or should have discovered that
25 those drugs were unreasonably dangerous and defective, and that other
26 practical and medically-feasible alternatives that were safer were available.

27 509. If the Innovator and Brand Defendants had not breached those duties, and had more
28 timely withdrawn their Propoxyphene Products from the market for reasons of safety and efficacy,
the FDA would have also required the withdrawal of all generic Propoxyphene Products.

1 510. If this had occurred, the Generic Defendants' unreasonably dangerous and defective
2 Propoxyphene Products would not have been on the market for Plaintiffs to purchase and ingest, and
3 Plaintiffs would not have suffered the injuries described above.

4 511. Because of these breaches, however, the Generic Defendants' unreasonably dangerous
5 and defective Propoxyphene Products were on the market, and Plaintiffs purchased and ingested them
6 in a reasonably foreseeable manner and substantially as intended by the Innovator and Brand
7 Defendants.

8 512. As a direct and proximate result, Plaintiffs suffered the injuries described above.

9 513. It was foreseeable that if the Innovator and Brand Defendants did not timely withdraw
10 their brand Propoxyphene Products from the market for reasons of safety and efficacy, that the FDA
11 would allow the generic Propoxyphene Products to also remain on the market, and that persons like
12 Plaintiffs would be prescribed Propoxyphene Products, and would purchase and ingest the Generic
13 Defendants' Propoxyphene Products, and, as a direct and proximate result, suffer the injuries that
14 Plaintiffs suffered.

15 514. Through the actions and inactions described above, the Innovator and Brand
16 Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a
17 profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive
18 damages.

19 515. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
20 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
21 withdraw these products from the market or to stop selling the products.

22 516. As a direct and proximate result of the defective manufacturing and the unreasonably
23 dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with
24 federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein
25 alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
26 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
27 and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs
28 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as

1 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
2 future.

3 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
4 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
5 the Court deems proper.

6 **EIGHTEENTH CAUSE OF ACTION**
7 **FRAUDULENT NONDISCLOSURE**
(Against Innovator and Brand Defendants)

8 517. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
9 Complaint.

10 518. At all relevant times, the Innovator and Brand Defendants were engaged in the
11 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
12 distributing, selling, supplying, marketing and/or promoting Darvocet and/or Darvon, brand-name
13 Propoxyphene Products.

14 519. At all relevant times, the Innovator and Brand Defendants had a duty to:

- 15 a. assess, manage and communicate the risks, dangers and adverse effects
16 associated with their Propoxyphene Products to the health care community and
17 the general public, including Plaintiffs and their prescribing physicians; and
18 b. distribute their Propoxyphene Products with adequate information about the
19 appropriate use of the products and their associated risks provided to the
20 general public and the health care community, including Plaintiffs and their
21 prescribing physicians.

22 520. At all relevant times, the Innovator and Brand Defendants knew that physicians who
23 prescribe drugs to their patients, in making their decisions on what to prescribe, often rely on the
24 statements made about the brand formulations of a drug, and thus that the physicians who prescribed
25 either brand or generic Propoxyphene Products to their patients were relying on the statements that
26 the Innovator and Brand Defendants made about Darvocet and/or Darvon.

27 521. At all relevant times, the Innovator and Brand Defendants knew that patients who are
28 prescribed a brand formulation of a drug are more likely to purchase the generic than the brand

1 formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely would have
2 instead purchased a generic formulation of Darvocet and/or Darvon.

3 522. Because of this knowledge, the duties of the Innovator and Brand Defendants that are
4 outlined above applied at all relevant times not only to the purchasers of the brand products and their
5 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
6 prescribing physicians, including Plaintiffs and their prescribing physicians.

7 523. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
8 ingestion of generic Propoxyphene Products.

9 524. Before Plaintiffs was injured by ingesting the Generic Defendants' Propoxyphene
10 Products, the Innovator and Brand Defendants knew that:

- 11 a. propoxyphene had not been adequately tested;
- 12 b. Propoxyphene Products were associated with a greatly increased risk of serious
13 adverse cardiovascular events that could result in death, which outweighed
14 their benefit for pain relief;
- 15 c. the risks, and the nature, scope, severity and duration of any serious side
16 effects, were greater with Propoxyphene Products than with other practical,
17 medically feasible and available pain management medications;
- 18 d. Propoxyphene Products were unreasonably dangerous to the health of patients
19 suffering from pain; and
- 20 e. Propoxyphene Products were no more effective for pain management than
21 other available, practical, and medically-feasible alternate pain management
22 medications, such as over-the-counter acetaminophen (brand name Tylenol),
23 which posed less risk.

24 525. At all relevant times, the Innovator and Brand Defendants knew that the risks
25 associated with Propoxyphene Products, and the ability to avoid them by using other available,
26 practical and medically-feasible pain management medications, were beyond that which would be
27 contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary
28 consumer who purchased Propoxyphene Products.

1 526. More specifically, the Innovator and Brand Defendants knew that the general public
2 and the health care community – including Plaintiffs and their prescribing physicians – would not
3 have been aware of the information outlined above, absent disclosures from the Innovator and Brand
4 Defendants, because:

- 5
- 6 a. the general public and the health care community did not have access to the
7 same resources, analysis and knowledge as the Innovator and Brand
8 Defendants; and
- 9 b. the Innovator and Brand Defendants manufactured, sold and distributed
10 Propoxyphene Products, and would therefore be assumed to have superior
11 knowledge about them.

12 527. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
13 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
14 alternate pain management medications.

15 528. At all relevant times, the Innovator and Brand Defendants failed to adequately disclose
16 to the general public or the medical community – including Plaintiffs and their treating physicians –
17 about any of the risks outlined above, or about the availability of practical and medically-feasible
18 alternatives.

19 529. More specifically, the Innovator and Brand Defendants failed to adequately disclose to
20 the general public or the medical community – including Plaintiffs and their treating physicians,
21 about the following facts that it knew:

- 22 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
23 was not significantly superior to placebo in managing pain, acetaminophen
24 alone was;
- 25 b. In 1978, the Health Research Group filed a petition with the FDA requesting
26 the recall of Darvon based on its claim that it was a dangerous drug of
27 questionable effectiveness, and subsequently submitted studies supporting that
28 propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased
withdrawal of propoxyphene-containing products because they were concerned

1 about the cardiac effects associated with their use and were unable to identify
2 any patient group in whom the risk benefit ratio may be positive;

- 3 d. In June 2009, the European Medicines Agency recommended withdrawal
4 across the European Union of marketing authorizations for propoxyphene-
5 containing medications because available evidence suggested that
6 acetaminophen alone was as effective as an acetaminophen-propoxyphene
7 combination, and that the benefits of medicines containing propoxyphene,
8 either alone or in combination, did not outweigh their risks.
- 9 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
10 concerning the risk of fatal overdose, and to add warnings to its label about
11 propoxyphene's dangers overall, for elderly patients, and in terms of its
12 potential for abuse and dependence.
- 13 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
14 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
15 MedGuide to highlight important safeguards for use of the drug, and to issue a
16 Public Health Advisory to underscore safety issues.
- 17 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
18 significant changes to the heart, even when taken at recommended doses.

19 530. Upon information and belief, the Innovator and Brand Defendants did not comply with
20 the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory. The failure to take
21 these actions resulted in inadequate labeling of all Propoxyphene based pharmaceuticals.

22 531. Upon information and belief, the Innovator and Brand Defendants also did not timely
23 implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the
24 information in the PDR, or communicate the information to prescribing physicians in Dear Health
25 Care Professional letters or by other means. The failure to take these actions resulted in inadequate
26 labeling of all Propoxyphene based pharmaceuticals.

27 532. It would have been technologically feasible, and would not have been cost-prohibitive,
28 for the Innovator and Brand Defendants to include adequate disclosures in their marketing and
29 labeling materials, and in their communications to the general public and the health care community.

30 533. The Innovator and Brand Defendants instead used their resources to conceal and
31 downplay the risks associated with Propoxyphene Products in their promotional materials,
32 instructional materials, labeling for, and communications about Propoxyphene Products, which was

1 especially misleading given their past and continued efforts to promote the safety and effectiveness of
2 the drugs.

3 534. The Innovator and Brand Defendants failed to disclose the material information
4 outlined above because they wanted the general public and the health care community – including
5 Plaintiffs and their prescribing physicians – to believe that Propoxyphene Products were safe and
6 effective, and wanted to induce medical providers – including Plaintiffs’ prescribing physicians – to
7 prescribe Propoxyphene Products, and consumers – including Plaintiffs – to request or not resist
8 those prescriptions.

9 535. Plaintiffs and their prescribing physicians justifiably relied on the lack of information
10 about the risks associated with Propoxyphene Products and/or about other available, practical and
11 medically-feasible pain management medications, and acted upon it, by Plaintiffs’ physicians
12 prescribing Propoxyphene Products, and Plaintiffs requesting or not resisting those prescriptions.

13 536. Had the Innovator and Brand Defendants provided adequate disclosures:

- 14
- 15 a. Plaintiffs’ physicians would not have prescribed Propoxyphene Products, and
16 would have instead prescribed another pain management medication that
17 neither contained propoxyphene nor involved an increased risk of serious
18 adverse cardiovascular events that could result in death, or recommended that
19 Plaintiffs instead take over-the-counter acetaminophen;
 - 20 b. Plaintiffs would not have purchased or ingested the Generic Defendants’
21 Propoxyphene Products; and
 - 22 c. Plaintiffs would not have suffered the injuries described above.

23 537. In light of what the Innovator and Brand Defendants knew, they had to have known or
24 anticipated that their failure to adequately disclose the dangers of propoxyphene and Propoxyphene
25 Products, and the availability of practical and medically-feasible alternate pain management
26 medications that posed less risk, would likely result in physicians prescribing Propoxyphene
27 Products, and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct
28 and proximate result, suffering serious adverse cardiovascular effects that could result in death.

1 538. Plaintiffs' prescription for and purchase and ingestion of the Generic Defendants'
2 Propoxyphene Products, and the injuries described above that followed, were the direct and
3 proximate result of the Innovator and Brand Defendants' knowing failure to disclose.

4 539. By failing to make the disclosures outlined above, the Innovator and Brand
5 Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a
6 profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive
7 damages.

8 540. Upon information and belief, Plaintiffs allege that Defendants actively and
9 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
10 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
11 Plaintiffs, from discovering these hazards.

12 541. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
13 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
14 withdraw these products from the market or to stop selling the products.

15 542. As a direct and proximate result of the defective manufacturing and the unreasonably
16 dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to
17 comply with federal standards and requirements, the Plaintiffs suffered severe and permanent
18 injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
19 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
20 and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiffs
21 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
22 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
23 future.

24 543. Defendants acted willfully or with gross negligence indicating a wanton disregard for
25 the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The
26 aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate
27 disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs
28

1 to punitive damages in an amount appropriate to punish the Defendants and deter them from similar
2 conduct in the future.

3 544. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
4 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
5 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
6 them from similar conduct in the future.

7 WHEREFORE Plaintiffs demand judgment against Defendants for compensatory, statutory,
8 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
9 the Court deems proper.

10 **NINETEENTH CAUSE OF ACTION**
11 **NEGLIGENT MISREPRESENTATION**
12 **(Against Innovator and Brand Defendants)**

13 545. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
14 Complaint.

15 546. At all relevant times, the Innovator and Brand Defendants were engaged in the
16 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
17 distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name
18 Propoxyphene Products.

19 547. At all relevant times, the Innovator and Brand Defendants had a duty to:

- 20 a. assess, manage and communicate the risks, dangers and adverse effects
21 associated with their Propoxyphene Products to the health care community and
22 the general public, including Plaintiffs and their prescribing physicians; and
23 b. distribute their Propoxyphene Products with adequate information about the
24 appropriate use of the products and their associated risks provided to the
25 general public and the health care community, including Plaintiffs and their
26 prescribing physicians.

27 548. At all relevant times, the Innovator and Brand Defendants knew or should have known
28 that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe,
often rely on the statements made about the brand formulations of a drug, and thus that the physicians

1 who prescribed either brand or generic Propoxyphene Products to their patients were relying on the
 2 statements that the Innovator and Brand Defendants made about Darvocet and/or Darvon.

3 549. At all relevant times, the Innovator and Brand Defendants knew or should have known
 4 that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic
 5 than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely
 6 would have instead purchased a generic formulation of Darvocet and/or Darvon.

7 550. Because of this knowledge, the duties of the Innovator and Brand Defendants that are
 8 outlined above applied at all relevant times not only to the purchasers of the brand products and their
 9 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
 10 prescribing physicians, including Plaintiffs and their prescribing physicians.

11 551. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
 12 ingestion of generic Propoxyphene Products.

13 552. Before Plaintiffs were injured by ingesting the Generic Defendants' Propoxyphene
 14 Products, the Innovator and Brand Defendants knew or should have known that:

- 15 a. propoxyphene had not been adequately tested;
- 16 b. Propoxyphene Products were associated with a greatly increased risk of serious
 17 adverse cardiovascular events that could result in death, which outweighed
 18 their benefit for pain relief;
- 19 c. the risks, and the nature, scope, severity and duration of any serious side
 20 effects, were greater with Propoxyphene Products than with other practical,
 21 medically feasible and available pain management medications;
- 22 d. Propoxyphene Products were unreasonably dangerous to the health of patients
 23 suffering from pain; and
- 24 e. Propoxyphene Products were no more effective for pain management than
 25 other available, practical, and medically-feasible alternate pain management
 26 medications, such as over-the-counter acetaminophen (brand name Tylenol),
 27 which posed less risk.

28 553. More specifically, the Innovator and Brand Defendants knew or should have known
 that:

- a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;
- b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks.
- e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.
- f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.
- g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

554. Despite what the Innovator and Brand Defendants knew or should have known, upon information and belief, the Innovator and Brand Defendants represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional material and labeling that:

- a. propoxyphene had been adequately tested;
- b. Propoxyphene Products were safe and effective for pain management; and
- c. Propoxyphene Products were more effective for pain management than other pain management medications.

1 555. Upon information and belief, these representations made by the Innovator and Brand
2 Defendants were false at the time that they were made, and the Innovator and Brand Defendants
3 knew or should have known that they were false.

4 556. Because of what the Innovator and Brand Defendants knew or should have known, as
5 described above, they failed to exercise reasonable care or competence in making these
6 misrepresentations.

7 557. The Innovator and Brand Defendants knew or should have known that the general
8 public and the health care community – including Plaintiffs and their prescribing physicians – would
9 not have been aware that their statements about the testing, safety and effectiveness associated with
10 Propoxyphene Products were false, and would have instead justifiably relied on them, because:

- 11
- 12 a. the general public and the health care community did not have access to the
13 same resources, analysis and knowledge as the Innovator and Brand
Defendants; and
 - 14 b. the Innovator and Brand Defendants manufactured, sold and distributed
15 Propoxyphene Products, and would therefore be assumed to have superior
16 knowledge about them.

17 558. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know
18 that the Innovator and Brand Defendants' misrepresentations were false.

19 559. Because of what the Innovator and Brand Defendants knew or should have known, as
20 described above, they failed to exercise reasonable care or competence in making these
21 misrepresentations.

22 560. Plaintiffs and their prescribing physicians justifiably relied and acted upon the
23 Innovator and Brand Defendants' misrepresentations, by Plaintiffs' physicians prescribing
24 Propoxyphene Products, and Plaintiffs purchasing and ingesting Propoxyphene Products.

25 561. Had the Innovator and Brand Defendants not made these misrepresentations:

- 26
- 27 a. Plaintiffs' physicians would not have prescribed Propoxyphene Products, and
28 would have instead prescribed another pain management medication that
neither contained propoxyphene nor involved an increased risk of serious

adverse cardiovascular events that could result in death, or recommended that Plaintiffs instead take over-the-counter acetaminophen;

b. Plaintiffs would not have purchased or ingested the Generic Defendants' Propoxyphene Products; and

c. Plaintiffs would not have suffered the injuries described above.

562. In light of what the Innovator and Brand Defendants knew or should have known, they should have anticipated that their misrepresentations would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

563. Plaintiffs' prescription for and purchase and ingestion of Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of the Innovator and Brand Defendants' misrepresentations.

564. By making the misrepresentations described above, the Innovator and Brand Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

565. At all relevant times herein, Defendants had full knowledge of the true cardiac risks associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to withdraw these products from the market or to stop selling the products.

566. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will

1 continue into the future.

2 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
3 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
4 the Court deems proper.

5
6 **TWENTIETH CAUSE OF ACTION**
7 **FRAUDULENT MISREPRESENTATION AND CONCEALMENT**
8 **(Against Innovator and Brand Defendants)**

9 567. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
10 Complaint.

11 568. At all relevant times, the Innovator and Brand Defendants were engaged in the
12 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
13 distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name
14 Propoxyphene Products.

15 569. At all relevant times, the Innovator and Brand Defendants had a duty to:

- 16 a. assess, manage and communicate the risks, dangers and adverse effects
17 associated with their Propoxyphene Products to the health care
18 community and the general public, including Plaintiffs and their
19 prescribing physicians; and
- 20 b. distribute their Propoxyphene Products with adequate information
21 about the appropriate use of the products and their associated risks
22 provided to the general public and the health care community,
23 including Plaintiffs and their prescribing physicians.

24 570. At all relevant times, the Innovator and Brand Defendants knew or should have known
25 that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe,
26 often rely on the statements made about the brand formulations of a drug, and thus that the physicians
27 who prescribed either brand or generic Propoxyphene Products to their patients were relying on the
28 statements that the Innovator and Brand Defendants made about Darvocet and/or Darvon.

571. At all relevant times, the Innovator and Brand Defendants knew or should have known
that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic

1 than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely
2 would have instead purchased a generic formulation of Darvocet and/or Darvon.

3 572. Because of this knowledge, the duties of the Innovator and Brand Defendants that are
4 outlined above applied at all relevant times not only to the purchasers of the brand products and their
5 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
6 prescribing physicians, including Plaintiffs and their prescribing physicians.

7 573. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
8 ingestion of generic Propoxyphene Products.

9 574. Before Plaintiffs were injured by ingesting the Generic Defendants' Propoxyphene
10 Products, the Innovator and Brand Defendants knew that:

- 12 a. propoxyphene had not been adequately tested;
- 13 b. Propoxyphene Products were associated with a greatly increased risk of
14 serious adverse cardiovascular events that could result in death, which
15 outweighed their benefit for pain relief;
- 16 c. the risks, and the nature, scope, severity and duration of any serious
17 side effects, were greater with Propoxyphene Products than with other
18 practical, medically feasible and available pain management
19 medications;
- 20 d. Propoxyphene Products were unreasonably dangerous to the health of
21 patients suffering from pain; and
- 22 e. Propoxyphene Products were no more effective for pain management
23 than other available, practical, and medically-feasible alternate pain
24 management medications, such as over-the-counter acetaminophen
25 (brand name Tylenol), which posed less risk.

26 575. More specifically, the Innovator and Brand Defendants knew that:

- 27 a. In 1971, six out of seven trials demonstrated that while propoxyphene
28 alone was not significantly superior to placebo in managing pain,
acetaminophen alone was;
- b. In 1978, the Health Research Group filed a petition with the FDA
requesting the recall of Darvon based on its claim that it was a
dangerous drug of questionable effectiveness, and subsequently
submitted studies supporting that propoxyphene could be toxic to the
cardiovascular system;

- c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks.
- e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.
- f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.
- g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

576. Despite what the Innovator and Brand Defendants knew, upon information and belief, the Innovator and Brand Defendants falsely represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional material and labeling that:

- a. propoxyphene had been adequately tested;
- b. Propoxyphene Products were safe and effective for pain management; and
- c. Propoxyphene Products were more effective for pain management than other pain management medications.

1 577. Upon information and belief, these representations were all intentionally false and
2 misleading at the time they were made, and the Innovator and Brand Defendants knew that they were
3 false and misleading, and willfully, wantonly and recklessly disregarded that they were false.

4 578. The Innovator and Brand Defendants knew that the general public and the health care
5 community – including Plaintiffs and their prescribing physicians – would not have been aware that
6 their statements about the testing, safety and effectiveness associated with Propoxyphene Products
7 were false, and would have instead justifiably relied on them, because:

- 8 a. the general public and the health care community did not have access to
9 the same resources, analysis and knowledge as the Innovator and Brand
10 Defendants; and
11 b. the Innovator and Brand Defendants manufactured, sold and distributed
12 Propoxyphene Products, and would therefore be assumed to have
superior knowledge about them.

13 579. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know
14 that the Innovator and Brand Defendants' misrepresentations were false.

15 580. The Innovator and Brand Defendants made these material misrepresentations because
16 they wanted the general public and the health care community to rely on them, and wanted to induce
17 medical providers – including Plaintiffs' treating physicians – to prescribe Propoxyphene Products,
18 and consumers – including Plaintiffs – to request or not resist those prescription.
19

20 581. Plaintiffs and their prescribing physicians justifiably relied and acted upon the
21 Innovator and Brand Defendants' misrepresentations, by Plaintiffs' physicians prescribing
22 Propoxyphene Products, and Plaintiffs requesting or not resisting that prescription.

23 582. Had the Innovator and Brand Defendants not made these misrepresentations:

- 24 a. Plaintiffs' physicians would not have prescribed Propoxyphene
25 Products, and would have instead prescribed another pain management
26 medication that neither contained propoxyphene nor involved an
27 increased risk of serious adverse cardiovascular events that could result
28 in death, or recommended that Plaintiffs instead take over-the-counter
acetaminophen;

1 b. Plaintiffs would not have purchased or ingested the Generic
2 Defendants' Propoxyphene Products; and

3 c. Plaintiffs would not have suffered the injuries described above.

4 583. In light of what the Innovator and Brand Defendants knew, they had to have known
5 that their misrepresentations would likely result in physicians prescribing Propoxyphene Products,
6 and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct and
7 proximate result, suffering serious adverse cardiovascular effects that could result in death.

8 584. Plaintiffs' prescription for and purchase and ingestion of Propoxyphene Products, and
9 the injuries described above that followed, were the direct and proximate result of the Innovator and
10 Brand Defendants' knowing misrepresentations.

11 585. By making the misrepresentations described above, the Innovator and Brand
12 Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a
13 profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive
14 damages.

15 586. Upon information and belief, Plaintiffs allege that Defendants actively and
16 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
17 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
18 Plaintiffs, from discovery these hazards.

19 587. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
20 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
21 withdraw these products from the market or to stop selling the products.

22 588. As a direct and proximate result of the defective manufacturing and the unreasonably
23 dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to
24 comply with federal standards and requirements, the Plaintiffs suffered severe and permanent
25 injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
26 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
27 28

1 and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiffs
 2 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
 3 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
 4 future.

5 589. Defendants acted willfully or with gross negligence indicating a wanton disregard for
 6 the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The
 7 aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate
 8 disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs
 9 to punitive damages in an amount appropriate to punish the Defendants and deter them from similar
 10 conduct in the future.

12 590. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
 13 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
 14 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
 15 them from similar conduct in the future.

17 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 18 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
 19 the Court deems proper.

20 **TWENTY-FIRST CAUSE OF ACTION**

21 **STRICT LIABILITY: STATE OF ALABAMA**

22 Code of Alabama §§ 6-5-500 through 6-5-504 and 6-5-520 through 6-5-525

(Against All Defendants)

23 (Applies to Plaintiffs whose Cause of Action Arose in the State of Alabama)

24 591. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 25 complaint.

26 592. Pursuant to the Alabama Code as well as the Alabama Extended Manufacturer
 27 Liability Doctrine, as adopted by the Alabama Supreme Court in 1976, Alabama plaintiffs claim
 28 damages and personal injury as a result of ingestion of unreasonably dangerous propoxyphene

1 containing products. Further, Defendants' actions and omissions as identified in this Complaint
 2 constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages
 3 pursuant to the common law and/or Title 6, Article, 2, inclusive, of the Code of Alabama 1975.

4 593. Defendants were engaged in the business of manufacturing, distributing, selling and
 5 promoting defective propoxyphene containing medications in the state of Alabama.

6 594. The propoxyphene containing pain medication was in a defective condition
 7 unreasonably dangerous to the consumer user in that it had a defective warning, and a defective
 8 design.

9 595. The defective propoxyphene containing product caused the plaintiff's injuries.

10 596. The defective design of the propoxyphene containing product existed at the time of the
 11 sale and the defective propoxyphene containing product had a defective warning at the time of the
 12 sale.

13 597. The product was expected to and did reach the plaintiff without substantial change in
 14 its condition.

15 598. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
 16 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
 17 withdraw these products from the market or to stop selling the products.

18 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 19 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
 20 the Court deems proper.

21 **TWENTY-SECOND CAUSE OF ACTION**
 22 **STRICT LIABILITY: STATE OF ARKANSAS**
 23 **Ark. Code Ann. § 16-116-102**
(Against All Defendants)

24 **(Applies to Plaintiffs whose Cause of Action Arose in the State of Arkansas)**

25 599. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 26 complaint.

27 600. Plaintiff is making a "product liability action" as defined by Ark. Code Ann. § 16-116-
 28 102(5), for damages caused by Plaintiff's use of propoxyphene containing pain medications, a

1 "product" as defined by Ark. Code Ann. § 16-116-102(4), manufactured, designed, sold, distributed,
 2 supplied and/or placed this product in the stream of commerce by Defendants who are
 3 "manufacturer[s]" as defined by Ark. Code Ann. § 16-116-102(3) and/or "seller[s]" as defined by
 4 Ark. Code Ann. § 16-116-102(6).

5 601. Propoxyphene containing pain medications are "unreasonably dangerous" as defined
 6 by Ark. Code Ann. § 16-116-102(7)(A) in that propoxyphene containing pain medications are more
 7 dangerous than what would be contemplated by an ordinary and reasonable consumer who uses
 8 propoxyphene containing pain medications.
 9

10 602. The propoxyphene containing pain medications manufactured, designed, sold,
 11 distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its
 12 design and had a deficient warning when it left the hands of Defendants in that it was unreasonably
 13 dangerous posing a serious risk of injury.
 14

15 603. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
 16 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
 17 withdraw these products from the market or to stop selling the products.

18 604. As a direct and proximate result of Plaintiff's use of propoxyphene containing pain
 19 medications as manufactured, designed, sold, supplied and introduced into the stream of commerce
 20 by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such
 21 harm.

22 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 23 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
 24 the Court deems proper.

25 **TWENTY-THIRD CAUSE OF ACTION**

26 **STRICT LIABILITY: STATE OF COLORADO**

27 **C.R.S.A. § 13-21-401 to § 13-21-406 and Restatement (Second) Torts, Section 402A**
 28 **(Against All Defendants)**

(Applies to Plaintiffs whose Cause of Action Arose in the State of Colorado)

1 605. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
2 complaint.

3 606. In addition to the traditional common law causes of action pled elsewhere in this
4 complaint, Plaintiffs whose injuries occurred in the State of Colorado also state that Defendants
5 violated section 402A of the Restatement (Second) of Torts. Specifically, these plaintiffs state that
6 the Propoxyphene ingested by them and manufactured and sold by defendants was in a defective
7 condition; that the defective condition made it unreasonably dangerous to its users; that the defect
8 existed at the time it left the control of the defendants; that the Propoxyphene was expected to and did
9 reach the Plaintiffs without any substantial unforeseeable change in its condition; and that the
10 defective condition was a legal cause of each of the Plaintiffs injuries.

11 607. Plaintiffs are making a "product liability action," as defined by C.R.S.A. § 13-21-
12 401(2) for damages caused by his/her use of propoxyphene containing pain medications, a product
13 manufactured, designed, sold, distributed, supplied and/or placed this product in the stream of
14 commerce by Defendants who are "manufacturer[s]" as defined by C.R.S.A. § 13-21-401(1) and/or
15 "seller[s]" as defined by C.R.S.A. § 13-21-401(3).

16 608. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of
17 the propoxyphene containing pain medications.

18 609. The propoxyphene containing pain medications manufactured and supplied by
19 Defendants was defective in design or formulation in that, when it left the hands of the Defendants,
20 the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or
21 it was more dangerous than an ordinary consumer would expect.

22 610. The propoxyphene containing pain medications that the Plaintiff used had not been
23 materially altered or modified prior to their use.

24 611. The foreseeable risks associated with the design or formulation of propoxyphene
25 containing pain medications, include, but are not limited to, the fact that the design or formulation of
26 propoxyphene containing pain medications is more dangerous than a reasonably prudent consumer
27 would expect when used in an intended or reasonably foreseeable manner.

1 612. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
2 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
3 withdraw these products from the market or to stop selling the products.

4 613. As a direct and proximate result of Plaintiff's use of propoxyphene containing pain
5 medications as manufactured, designed, sold, supplied, marketed and introduced into the stream of
6 commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to
7 suffer such harm, damages and economic loss in the future.

8 614. Additionally, to the extent any claims are made under the laws of the State of
9 Colorado, including but not necessarily the claims of Plaintiff, and to the extent this Court finds that
10 Colorado statutory law found at C.R.S.A. § 13-21-401 to § 13-21-406 is applicable to this case,
11 Plaintiff asserts and alleges that the presumptions found at C.R.S.A. § 13-21-403 are inapplicable.

12 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
13 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
14 the Court deems proper.

15 **TWENTY-FOURTH CAUSE OF ACTION**
16 **STRICT LIABILITY: STATE OF FLORIDA**
17 Restatement (Second) Torts, Section 402A
18 (Against All Defendants)

19 (Applies to Plaintiffs whose Cause of Action Arose in the State of Florida)

20 615. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
21 complaint.

22 616. In addition to the traditional common law causes of action pled elsewhere in this
23 complaint, Plaintiffs whose injuries occurred in the State of Florida also state that Defendants
24 violated section 402A of the Restatement (Second) of Torts. Specifically, these plaintiffs state that
25 the Propoxyphene ingested by them and manufactured and sold by defendants was in a defective
26 condition; that the defective condition made it unreasonably dangerous to its users; that the defect
27 existed at the time it left the control of the defendants; that the Propoxyphene was expected to and did
28

1 reach the Plaintiffs without any substantial unforeseeable change in its condition; and that the
2 defective condition was a legal cause of each of the Plaintiffs injuries.

3 617. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
4 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
5 withdraw these products from the market or to stop selling the products.

6 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
7 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
8 the Court deems proper.
9

10 **TWENTY-FIFTH CAUSE OF ACTION**
11 **LIABILITY: STATE OF GEORGIA**
12 **§ 51-1-11 OF THE GEORGIA CODE**
13 **(Against All Defendants)**

14 **(Applies to Plaintiffs whose Cause of Action Arose in the State of Georgia)**

15 618. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
16 complaint.

17 619. For the reasons set forth above, Plaintiffs assert and allege that Defendants are liable
18 to Plaintiffs under Section 51-1-11 of the Georgia Code because Defendants' Propoxyphene
19 containing medications were not merchantable or reasonably suited for their intended use at the time
20 of sale to Plaintiffs, and this condition is the proximate cause of Plaintiffs' injuries.

21 620. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
22 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
23 withdraw these products from the market or to stop selling the products.

24 621. As a direct and proximate result of Plaintiffs' use of the Propoxyphene medication,
25 Plaintiffs suffered harm, damages and economic loss and will continue to suffer such harm, damages
26 and economic loss in the future.

27 622. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages
28 pursuant to the common law and applicable state statutes.

1 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
2 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
3 the Court deems proper.

4 **TWENTY-SIXTH CAUSE OF ACTION**
5 **STRICT LIABILITY: STATE OF ILLINOIS**
6 **Restatement (Second) Torts, Section 402A**
7 **(Against All Defendants)**

8 **(Applies to Plaintiffs whose Cause of Action Arose in the State of Illinois)**

9 623. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
10 complaint.

11 624. In addition to the traditional common law causes of action pled elsewhere in this
12 complaint, Plaintiffs whose injuries occurred in the State of Illinois also state that Defendants
13 violated section 402A of the Restatement (Second) of Torts. Specifically, these plaintiffs state that
14 the Propoxyphene ingested by them and manufactured and sold by defendants was in a defective
15 condition; that the defective condition made it unreasonably dangerous to its users; that the defect
16 existed at the time it left the control of the defendants; that the Propoxyphene was expected to and did
17 reach the Plaintiffs without any substantial unforeseeable change in its condition; and that the
18 defective condition was a legal cause of each of the Plaintiffs injuries.

19 625. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
20 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
21 withdraw these products from the market or to stop selling the products.

22 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
23 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
24 the Court deems proper.

25 **TWENTY-SEVENTH CAUSE OF ACTION**
26 **STRICT LIABILITY: STATE OF INDIANA**
27 **CLAIMS UNDER THE IPLA: Ind. Code. Ann. §24-20 et seq.**
28 **(Against All Defendants)**

(Applies to Plaintiffs whose Cause of Action Arose in the State of Indiana)

1 626. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
2 complaint.

3 627. Defendants placed into the stream of commerce propoxyphene containing pain
4 medication that was in a defective condition unreasonably dangerous to plaintiffs in that it was
5 defectively designed and had a defective warning.

6 628. The plaintiffs are in a class of people that defendants should reasonably foresee as
7 being subject to the harm caused by the defective condition; the defendants are engaged in the
8 business of manufacturing, marketing, and selling Propoxyphene containing pain medication; and the
9 Propoxyphene containing pain medication reached the plaintiffs without substantial alteration in
10 condition.

11 629. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
12 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
13 withdraw these products from the market or to stop selling the products.

14 630. Defendants defective product caused the plaintiffs to suffer injury and damages as
15 described in this complaint.

16 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
17 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
18 the Court deems proper.

19
20
21 **TWENTY-EIGHTH CAUSE OF ACTION**

22 **LIABILITY: STATE OF KANSAS**

23 K.S.A. § 60-3302 et seq.

24 (Against All Defendants)

25 (Applies to Plaintiffs whose Cause of Action Arose in the State of Kansas)

26 631. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
27 complaint.

28 632. Plaintiffs are making a "product liability claim" as defined by K.S.A. § 60-3302(c)
because she suffered "harm" as defined by K.S.A. § 60-3302(d) caused by Plaintiffs' use of

1 Propoxyphene containing medication, manufactured, designed, sold, distributed, supplied and/or
 2 placed this product in the stream of commerce by Defendants who are "manufacturer[s]" as defined
 3 by K.S.A. § 60-3302(b) and/or "product seller[s]" as defined by K.S.A. § 60-3302(a).

4 633. The Propoxyphene containing medications manufactured, designed, sold, distributed,
 5 supplied and/or placed in the stream of commerce by Defendants, was defective in its design and
 6 deficient in its warnings when it left the hands of Defendants in that it was unreasonably dangerous.

7 634. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
 8 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
 9 withdraw these products from the market or to stop selling the products.
 10

11 635. As a direct and proximate result of Plaintiff's use of the defendants' Propoxyphene
 12 containing medication Plaintiffs suffered harm, damages and economic loss and will continue to
 13 suffer such harm.

14 636. Additionally, Plaintiffs asserts and alleges that there is no applicable defense found at
 15 K.S.A. § 60-3304.
 16

17 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 18 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
 19 the Court deems proper.

20 **TWENTY-NINTH CAUSE OF ACTION**
 21 **STRICT LIABILITY: STATE OF MAINE**

22 **Strict Liability Pursuant to Me. Rev. Stat. Ann. tit 14, § 221 (2008)**

23 **(Against All Defendants)**

24 **(Applies to Plaintiffs whose Cause of Action Arose in the State of Maine)**

25 637. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 26 complaint.

27 638. Plaintiffs whose injuries occurred in the State of Maine allege strict liability as set out
 28 under Me. Rev. Stat. Ann. tit 14, 221 (2008). Plaintiffs allege that the propoxyphene containing
 medication was defectively designed and unreasonably dangerous and carried a defective warning.

1 The defective propoxyphene containing product caused the plaintiff's injuries. The product was
2 expected to and did reach the plaintiff without substantial change in its condition.

3 639. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
4 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
5 withdraw these products from the market or to stop selling the products.

6 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
7 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
8 the Court deems proper.
9

10 **THIRTIETH CAUSE OF ACTION**
11 **VIOLATION OF CONSUMER PROTECTION ACTS AND DECEPTIVE TRADE**
12 **PRACTICES ACTS**

13 640. Plaintiffs incorporates by reference each and every paragraph of this Complaint as if
14 fully set forth herein and further alleges as follows:

15 641. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade
16 practices in the design, development, manufacture, promotion, and sale of propoxyphene containing
17 medications.

18 642. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiffs
19 would not have purchased and/or paid for propoxyphene containing medications and would not have
20 incurred related medical costs.

21 643. Specifically, Plaintiffs were misled by the deceptive conduct described herein.

22 644. Defendants' deceptive, unconscionable, or fraudulent representations and material
23 omissions to consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices
24 in violation of the state consumer protection statutes listed below.

25 645. Defendants engaged in wrongful conduct while at the same time obtaining, under false
26 pretenses, substantial sums of money from Plaintiffs for propoxyphene containing medications that
27 they would not have paid had Defendants not engaged in unfair and deceptive conduct.
28

646. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of:

- a. Alabama Ala. Code §§8-19-1 through 8-19-15 (Deceptive Trade Practices Act);
- b. Arizona Ariz. Rev. Stat. Ann. §§44-1521 through 44-1534 (Consumer Fraud Act);
- c. Arkansas Ark. Code Ann. §§4-88-101 through 4-88-207 (Deceptive Trade Practices Act);
- d. California Cal. Civ. Code §§1750 through 1784 (Consumer Legal Remedies Act); Cal Bus. & Prof. Code §§17200 through 17594 (Unfair Competition Law);
- e. Colorado Colo. Rev. Stat. §§6-1-101 through 6-1-115 (Consumer Protection Act);
- f. Florida Fla. Stat. Ann. §§501.201 through 501.213 (Deceptive and Unfair Trade Practices Act);
- g. Georgia Ga. Code Ann. §§10-1-370 through 10-1-375 (Uniform Deceptive Trade Practices Act); Ga. Code Ann. §§10-1-390 through 10-1-407 (Fair Business Practices Act);
- h. Hawaii Haw. Rev. Stat. §§480-1 through 480-24; Haw. Rev. Stat. §§481A-1 through 481A-5 (Uniform Deceptive Trade Practices Act);
- i. Illinois 815 Ill. Comp. Stat. Ann. 505/1 through 505/12 (Consumer Fraud and Deceptive Business Practices Act); 815 Ill. Comp. Stat. Ann. 510/1 through 510/7 (Uniform Deceptive Trade Practices Act);
- j. Indiana Ind. Code Ann. §§24-5-0.5-1 through 25-5-0.5-12 (Deceptive Consumer Sales Act);
- k. Kansas Kan. Stat. Ann. §§50-623 through 50-640 and 50-676 through 50-679a (Consumer Protection Act);
- l. Maine Me. Rev. Stat. Ann. tit. 5, §§205-A through 214 (Unfair Trade Practices Act); Me. Rev. Stat. Ann. tit. 10, §§1211 through 1216 (Uniform Deceptive Trade Practices Act);
- m. Massachusetts Mass. Gen. Laws Ann. ch. 93A, §§1 through 11 (Regulation of Business Practice and Consumer Protection Act);

1 647. Plaintiffs were injured by the cumulative and indivisible nature of Defendants'
2 conduct. The cumulative effect of Defendants' conduct directed at consumers including Plaintiffs was
3 to create a demand for and sell propoxyphene containing medications. Each aspect of Defendants'
4 conduct combined to artificially create sales of propoxyphene containing medications.

5 648. Consumers relied upon Defendants' misrepresentations and omissions in determining
6 which propoxyphene containing medications to purchase.

7 649. By reason of the unlawful acts engaged in by Defendants, Plaintiffs have suffered
8 ascertainable loss and damages.

9 650. At all relevant times herein, Defendants had full knowledge of the true cardiac risks
10 associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to
11 withdraw these products from the market or to stop selling the products.

12 651. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs were
13 damaged by paying in whole or in part for Defendants' propoxyphene containing medications.

14 652. As a direct and proximate result of Defendants' violations of the above states'
15 consumer protection statutes, Plaintiffs have sustained economic losses and other damages for which
16 they are entitled to statutory and compensatory damages, and declaratory relief, in an amount to be
17 proven at trial.

18 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
19 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
20 the Court deems proper.

21 **THIRTY-FIRST CAUSE OF ACTION**
22 **PUNITIVE DAMAGES**

23 653. At all times material hereto, the Defendants knew or should have known that the
24 administration of propoxyphene could result in the development of including, but not limited to, an
25 increased risk of serious adverse cardiovascular events that could result in death.
26
27
28

1 654. At all times material hereto, the Defendants attempted to misrepresent and did
2 misrepresent facts concerning the safety and efficacy of propoxyphene and products containing
3 propoxyphene.

4 655. Defendants' misrepresentations included knowingly withholding material information
5 from the medical community and the public, including Plaintiffs herein, concerning the safety of
6 propoxyphene.

7 656. At all times material hereto, the Defendants knew and recklessly disregarded the fact
8 that propoxyphene and products containing propoxyphene could result in the development of
9 including, but not limited to, an increased risk of serious adverse cardiovascular events that could
10 result in death.

11 657. Notwithstanding the foregoing, the Defendants continued to aggressively market
12 products containing propoxyphene to consumers, including Plaintiffs herein, without disclosing the
13 fact that administration of propoxyphene could result in the development of including, but not limited
14 to, an increased risk of serious adverse cardiovascular events that could result in death.

15 658. The Defendants knew of the defective and unreasonably dangerous nature of products
16 containing propoxyphene as set forth herein, but continued to design, develop, manufacture, promote,
17 market, distribute, and sell it so as to maximize sales and profits at the expense of the health and
18 safety of the public, including Plaintiffs herein, in conscious and/or negligent disregard of the
19 foreseeable risks including, adverse cardiovascular events that could result in death.

20 659. Defendants intentionally concealed and/or recklessly failed to disclose to the public,
21 including Plaintiffs herein, the potentially life threatening side effects of the administration of
22 propoxyphene in order to ensure continued and increased sales.

23 660. The Defendants' intentional and/or reckless failure to disclose information deprived
24 Plaintiffs of necessary information to enable Plaintiffs and their healthcare providers to weigh the
25 true risks of using propoxyphene against its benefits.

661. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiffs, and the unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with federal standards and requirements, Plaintiffs suffered severe and permanent cardiovascular injuries, including death.

662. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise economically injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

663. At all relevant times herein, Defendants had full knowledge of the true cardiac risks associated with propoxyphene products, and despite this knowledge and the ability to do so, failed to withdraw these products from the market or to stop selling the products.

664. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitling Plaintiffs to punitive damages, as allowed by law and by state statute in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

THIRTY-SECOND CAUSE OF ACTION
WRONGFUL DEATH
(Against All Defendants)

665. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

666. Plaintiffs who are representatives of decedents bring this action as the representatives of Decedents' estates.

667. As a direct and proximate result of Defendants' conduct described above, Decedent suffered bodily injury resulting in reasonably necessary medical and hospital services, pain and suffering, death and funeral expenses.

668. As a direct and proximate result of Defendants' conduct described above, Decedents' beneficiaries have suffered and will continue indefinitely to suffer mental and physical anguish, and a loss of consortium.

669. Through the conduct alleged above, Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, punitive damages, and damages for wrongful death, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRTY-THIRD CAUSE OF ACTION
SURVIVAL
(Against All Defendants)

670. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

671. All Plaintiffs who are representatives of a decedent bring this action as the representatives of Decedents' estates.

672. . As a direct and proximate result of Defendants' conduct described above, Decedents suffered bodily injury resulting in reasonably necessary medical and hospital services, pain and suffering, death and funeral expenses.

673. As a direct and proximate result of Defendants' conduct described above, Decedents' beneficiaries have suffered and will continue indefinitely to suffer mental and physical anguish, and a loss of consortium.

674. Through the conduct alleged above, Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

1 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory,
 2 punitive damages, and damages for wrongful death, together with interest, costs of suit, attorneys'
 3 fees, and all such other relief as the Court deems proper.

4
 5 **Affirmative Defense of**
 6 **Comment k. to §402A of the Second Restatement of Torts**
 7 **Is not applicable to any Plaintiff's Claim**

8 675. In States that recognize Comment k. to the Restatement of Torts (Second), Comment
 9 K does not apply to provide any defendants an affirmative defense to strict liability or other cause of
 10 action.

11 676. Multiple alternative pain medications were available to Plaintiffs, that were safer than
 12 and just as effective as propoxyphene in managing pain. None the defendants chose to offer such
 13 safer alternatives in lieu of propoxyphene medications. Further, Defendants could have chosen to
 14 voluntarily withdraw the propoxyphene medications from the market prior to FDA action.

15 **MARKET SHARE LIABILITY**

16 677. Plaintiffs hereby incorporate by reference all allegations contained in the preceding
 17 paragraphs, as though fully set forth herein.

18 678. In this action, there may be certain plaintiffs in which the manufacturer of
 19 propoxyphene ingested before his or her injury cannot be identified due to no fault of their own.
 20 These situations may arise for example where the pharmacy or drug store has not maintained records
 21 of which manufacturer they bought the propoxyphene from. In other cases the pharmacy records
 22 may simply not be available for any number of reasons. In these cases, each Generic Defendant
 23 should bear a share of liability to the effected Plaintiff in an amount equal to its percentage of general
 24 market share at the time of the injury.

25 **PRESERVATION CLAIMS**

26 679. Many States have recently enacted tort reform statutes with "exclusive remedy"
 27 provisions. Courts have yet to determine whether these exclusive remedy provisions eliminate or
 28 supersede, to any extent, state common law claims. If during the pendency of this action this court
 makes any such determination, Plaintiffs hereby specifically makes claim to and preserves any State

1 claim based upon any exclusive remedy provision, under any state law this court may apply, to the
2 extent not already alleged above.

3 To the extent that Defendant(s) may claim that one or more of Plaintiffs' claims are barred by
4 the applicable statute of limitations, Plaintiff and each of them asserts that the statute of limitations is
5 and has been tolled by Plaintiff's discovery that his or her injury(ies) was/were caused by
6 Defendants' defective product and failure to properly and adequately warn of the products' risks, all
7 as more fully set forth in this Complaint, after the injuries sustained by each Plaintiff.

8 **PRAYER FOR RELIEF**

9 WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as
10 follows:

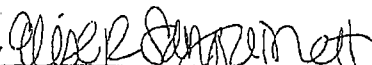
- 11 1. For an award of compensatory damages against Defendants for medical and hospital
- 12 expenses, funeral expenses, pain and suffering, loss of income or earning capacity, and other
- 13 damages according to proof at trial in excess of the jurisdictional minimum of this Court;
- 14 2. For an award of punitive or exemplary damages against Defendants in an amount sufficient
- 15 to punish and deter future similar conduct, according to statute and as allowed by law;
- 16 3. For reasonable attorneys' fees and costs;
- 17 4. For pre-judgment interest;
- 18 5. For leave to amend as additional facts are gathered; and
- 19 6. For such further and other relief the Court deems just, equitable, and proper.
- 20

21 Respectfully submitted,

22 DATED: November 15, 2012

23 KHORRAMI, LLP

24 By



25 ELISE R. SANGUINETTI
26 Attorneys for Plaintiffs
27
28

DEMAND FOR JURY TRIAL

Plaintiffs respectfully demand a trial by jury on all claims.

Respectfully submitted,

DATED: November 15, 2012

KHORRAMI, LLP

By Elise R. Sanguinetti
ELISE R. SANGUINETTI
Attorneys for Plaintiffs

ORIGINAL

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Elise R. Sanguinetti SBN 191389; Amanda J. Greenburg, SBN 255767 KHORRAMI LLP 360 22nd Street, Suite 640 Oakland, CA 94612 TELEPHONE NO.: 510-867-2000 FAX NO.: 510-867-2010		FOR COURT USE ONLY FILED Los Angeles Superior Court NOV 15 2012 John A. Clarke, Executive Officer/Clerk By <u>SHAUNYA WESLEY</u> , Deputy
ATTORNEY FOR (Name): SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES STREET ADDRESS: 111 North Hill Street MAILING ADDRESS: 111 North Hill Street CITY AND ZIP CODE: Los Angeles, CA 90012 BRANCH NAME: Stanley Mosk Courthouse--Central		
CASE NAME: Corber, et al. v. McKesson, et al.		
CIVIL CASE COVER SHEET <input checked="" type="checkbox"/> Unlimited (Amount demanded exceeds \$25,000)	<input type="checkbox"/> Limited (Amount demanded is \$25,000 or less)	CASE NUMBER: BC495753
Complex Case Designation <input type="checkbox"/> Counter <input type="checkbox"/> Joinder Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)		JUDGE: DEPT:

Items 1-6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:		
Auto Tort <input type="checkbox"/> Auto (22) <input type="checkbox"/> Uninsured motorist (46) Other P/DPD/W (Personal Injury/Property Damage/Wrongful Death) Tort <input type="checkbox"/> Asbestos (04) <input checked="" type="checkbox"/> Product liability (24) <input type="checkbox"/> Medical malpractice (45) <input type="checkbox"/> Other P/DPD/W (23) Non-P/DPD/W (Other) Tort <input type="checkbox"/> Business tort/unfair business practice (07) <input type="checkbox"/> Civil rights (08) <input type="checkbox"/> Defamation (13) <input type="checkbox"/> Fraud (16) <input type="checkbox"/> Intellectual property (19) <input type="checkbox"/> Professional negligence (25) <input type="checkbox"/> Other non-P/DPD/W tort (35) Employment <input type="checkbox"/> Wrongful termination (36) <input type="checkbox"/> Other employment (15)	Contract <input type="checkbox"/> Breach of contract/warranty (06) <input type="checkbox"/> Rule 3.740 collections (09) <input type="checkbox"/> Other collections (09) <input type="checkbox"/> Insurance coverage (18) <input type="checkbox"/> Other contract (37) Real Property <input type="checkbox"/> Eminent domain/inverse condemnation (14) <input type="checkbox"/> Wrongful eviction (33) <input type="checkbox"/> Other real property (26) Unlawful Detainer <input type="checkbox"/> Commercial (31) <input type="checkbox"/> Residential (32) <input type="checkbox"/> Drugs (38) Judicial Review <input type="checkbox"/> Asset forfeiture (05) <input type="checkbox"/> Petition re: arbitration award (11) <input type="checkbox"/> Writ of mandate (02) <input type="checkbox"/> Other judicial review (39)	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403) <input type="checkbox"/> Antitrust/Trade regulation (03) <input type="checkbox"/> Construction defect (10) <input checked="" type="checkbox"/> Mass tort (40) <input type="checkbox"/> Securities litigation (28) <input type="checkbox"/> Environmental/Toxic tort (30) <input type="checkbox"/> Insurance coverage claims arising from the above listed provisionally complex case types (41) Enforcement of Judgment <input type="checkbox"/> Enforcement of judgment (20) Miscellaneous Civil Complaint <input type="checkbox"/> RICO (27) <input type="checkbox"/> Other complaint (not specified above) (42) Miscellaneous Civil Petition <input type="checkbox"/> Partnership and corporate governance (21) <input type="checkbox"/> Other petition (not specified above) (43)

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2. This case ☒ is ☐ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
- a. ☒ Large number of separately represented parties d. ☒ Large number of witnesses
- b. ☒ Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve e. ☒ Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
- c. ☒ Substantial amount of documentary evidence f. ☐ Substantial postjudgment judicial supervision
3. Remedies sought (check all that apply): a. ☒ monetary b. ☐ nonmonetary; declaratory or injunctive relief c. ☒ punitive
4. Number of causes of action (specify):
5. This case ☐ is ☒ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. (You may use form CM-015.)

Date: November 15, 2012

Elise R. Sanguinetti

(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions. File this cover sheet in addition to any cover sheet required by local court rule. If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding. Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.	
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Los Angeles Superior Court
FILED

NOV 12 2012

By SHARON WESTLEY
Deputy
John A. Clarke, Executive Officer/Clerk

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CM-010

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you must complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check one box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the primary cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than \$25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort

Auto (22)—Personal Injury/Property Damage/Wrongful Death
Uninsured Motorist (46) (*if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto*)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort

Asbestos (04)
Asbestos Property Damage
Asbestos Personal Injury/Wrongful Death
Product Liability (*not asbestos or toxic/environmental*) (24)
Medical Malpractice (45)
Medical Malpractice—Physicians & Surgeons
Other Professional Health Care Malpractice
Other PI/PD/WD (23)
Premises Liability (e.g., slip and fall)
Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
Intentional Infliction of Emotional Distress
Negligent Infliction of Emotional Distress
Other PI/PD/WD

Non-PI/PD/WD (Other) Tort

Business Tort/Unfair Business Practice (07)
Civil Rights (e.g., discrimination, false arrest) (*not civil harassment*) (08)
Defamation (e.g., slander, libel) (13)

Fraud (16)

Intellectual Property (19)

Professional Negligence (25)

Legal Malpractice
Other Professional Malpractice (*not medical or legal*)

Other Non-PI/PD/WD Tort (35)

Employment

Wrongful Termination (36)

Other Employment (15)

Contract

Breach of Contract/Warranty (06)
Breach of Rental/Lease
Contract (*not unlawful detainer or wrongful eviction*)
Contract/Warranty Breach—Seller
Plaintiff (*not fraud or negligence*)
Negligent Breach of Contract/Warranty
Other Breach of Contract/Warranty
Collections (e.g., money owed, open book accounts) (09)
Collection Case—Seller Plaintiff
Other Promissory Note/Collections Case
Insurance Coverage (*not provisionally complex*) (18)
Auto Subrogation
Other Coverage
Other Contract (37)
Contractual Fraud
Other Contract Dispute

Real Property

Eminent Domain/Inverse Condemnation (14)
Wrongful Eviction (33)
Other Real Property (e.g., quiet title) (26)
Writ of Possession of Real Property
Mortgage Foreclosure
Quiet Title
Other Real Property (*not eminent domain, landlord/tenant, or foreclosure*)

Unlawful Detainer

Commercial (31)
Residential (32)
Drugs (38) (*if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential*)

Judicial Review

Asset Forfeiture (05)
Petition Re: Arbitration Award (11)
Writ of Mandate (02)
Writ—Administrative Mandamus
Writ—Mandamus on Limited Court Case Matter
Writ—Other Limited Court Case Review
Other Judicial Review (39)
Review of Health Officer Order
Notice of Appeal—Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)

Antitrust/Trade Regulation (03)
Construction Defect (10)
Claims Involving Mass Tort (40)
Securities Litigation (28)
Environmental/Toxic Tort (30)
Insurance Coverage Claims (*arising from provisionally complex case type listed above*) (41)

Enforcement of Judgment

Enforcement of Judgment (20)
Abstract of Judgment (Out of County)
Confession of Judgment (*non-domestic relations*)
Sister State Judgment
Administrative Agency Award (*not unpaid taxes*)
Petition/Certification of Entry of Judgment on Unpaid Taxes
Other Enforcement of Judgment Case

Miscellaneous Civil Complaint

RICO (27)
Other Complaint (*not specified above*) (42)
Declaratory Relief Only
Injunctive Relief Only (*non-harassment*)
Mechanics Lien
Other Commercial Complaint Case (*non-tort/non-complex*)
Other Civil Complaint (*non-tort/non-complex*)

Miscellaneous Civil Petition

Partnership and Corporate Governance (21)
Other Petition (*not specified above*) (43)
Civil Harassment
Workplace Violence
Elder/Dependent Adult Abuse
Election Contest
Petition for Name Change
Petition for Relief From Late Claim
Other Civil Petition

ORIGINAL

SHORT TITLE: Corber, et al. v. McKesson, et al.	CASE NUMBER
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**CIVIL CASE COVER SHEET ADDENDUM AND
STATEMENT OF LOCATION
(CERTIFICATE OF GROUNDS FOR ASSIGNMENT TO COURTHOUSE LOCATION)**

This form is required pursuant to Local Rule 2.0 in all new civil case filings in the Los Angeles Superior Court.

Item I. Check the types of hearing and fill in the estimated length of hearing expected for this case:

JURY TRIAL? ☒ YES CLASS ACTION? ☐ YES LIMITED CASE? ☐ YES TIME ESTIMATED FOR TRIAL 5 ☐ HOURS/ ☒ DAYS

Item II. Indicate the correct district and courthouse location (4 steps – If you checked "Limited Case", skip to Item III, Pg. 4):

Step 1: After first completing the Civil Case Cover Sheet form, find the main Civil Case Cover Sheet heading for your case in the left margin below, and, to the right in Column A, the Civil Case Cover Sheet case type you selected.

Step 2: Check one Superior Court type of action in Column B below which best describes the nature of this case.

Step 3: In Column C, circle the reason for the court location choice that applies to the type of action you have checked. For any exception to the court location, see Local Rule 2.0.

Applicable Reasons for Choosing Courthouse Location (see Column C below)

- | | |
|--|--|
| 1. Class actions must be filed in the Stanley Mosk Courthouse, central district. | 6. Location of property or permanently garaged vehicle. |
| 2. May be filed in central (other county, or no bodily injury/property damage). | 7. Location where petitioner resides. |
| 3. Location where cause of action arose. | 8. Location wherein defendant/respondent functions wholly. |
| 4. Location where bodily injury, death or damage occurred. | 9. Location where one or more of the parties reside. |
| 5. Location where performance required or defendant resides. | 10. Location of Labor Commissioner Office |

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Step 4: Fill in the information requested on page 4 in Item III; complete Item IV. Sign the declaration.

Auto Tort

Other Personal Injury/Property Damage/ Wrongful Death Tort

A Civil Case Cover Sheet Category No.	B Type of Action (Check only one)	C Applicable Reasons (See Step 3 Above)
Auto (22)	<input type="checkbox"/> A7100 Motor Vehicle - Personal Injury/Property Damage/Wrongful Death	1., 2., 4.
Uninsured Motorist (46)	<input type="checkbox"/> A7110 Personal Injury/Property Damage/Wrongful Death - Uninsured Motorist	1., 2., 4.
Asbestos (04)	<input type="checkbox"/> A6070 Asbestos Property Damage <input type="checkbox"/> A7221 Asbestos - Personal Injury/Wrongful Death	2. 2.
Product Liability (24)	<input checked="" type="checkbox"/> A7260 Product Liability (not asbestos or toxic/environmental)	1., 2., 3., 4., 8.
Medical Malpractice (45)	<input type="checkbox"/> A7210 Medical Malpractice - Physicians & Surgeons <input type="checkbox"/> A7240 Other Professional Health Care Malpractice	1., 4. 1., 4.
Other Personal Injury Property Damage Wrongful Death (23)	<input type="checkbox"/> A7250 Premises Liability (e.g., slip and fall) <input type="checkbox"/> A7230 Intentional Bodily Injury/Property Damage/Wrongful Death (e.g., assault, vandalism, etc.) <input type="checkbox"/> A7270 Intentional Infliction of Emotional Distress <input type="checkbox"/> A7220 Other Personal Injury/Property Damage/Wrongful Death	1., 4. 1., 4. 1., 3. 1., 4.

SHORT TITLE: Corber, et al. v. McKesson, et al.	CASE NUMBER
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	A Civil Case Cover Sheet Category No.	B Type of Action (Check only one)	C Applicable Reasons (See Step 3 Above)
Non-Personal Injury/ Property Damage/ Wrongful Death Tort	Business Tort (07)	<input type="checkbox"/> A6029 Other Commercial/Business Tort (not fraud/breach of contract)	1., 3.
	Civil Rights (08)	<input type="checkbox"/> A6005 Civil Rights/Discrimination	1., 2., 3.
	Defamation (13)	<input type="checkbox"/> A6010 Defamation (slander/libel)	1., 2., 3.
	Fraud (16)	<input type="checkbox"/> A6013 Fraud (no contract)	1., 2., 3.
	Professional Negligence (25)	<input type="checkbox"/> A6017 Legal Malpractice <input type="checkbox"/> A6050 Other Professional Malpractice (not medical or legal)	1., 2., 3. 1., 2., 3.
	Other (35)	<input type="checkbox"/> A6025 Other Non-Personal Injury/Property Damage tort	2., 3.
Employment	Wrongful Termination (36)	<input type="checkbox"/> A6037 Wrongful Termination	1., 2., 3.
	Other Employment (15)	<input type="checkbox"/> A6024 Other Employment Complaint Case <input type="checkbox"/> A6109 Labor Commissioner Appeals	1., 2., 3. 10.
Contract	Breach of Contract/ Warranty (06) (not insurance)	<input type="checkbox"/> A6004 Breach of Rental/Lease Contract (not unlawful detainer or wrongful eviction) <input type="checkbox"/> A6008 Contract/Warranty Breach -Seller Plaintiff (no fraud/negligence) <input type="checkbox"/> A6019 Negligent Breach of Contract/Warranty (no fraud) <input type="checkbox"/> A6028 Other Breach of Contract/Warranty (not fraud or negligence)	2., 5. 2., 5. 1., 2., 5. 1., 2., 5.
	Collections (09)	<input type="checkbox"/> A6002 Collections Case-Seller Plaintiff <input type="checkbox"/> A6012 Other Promissory Note/Collections Case	2., 5., 6. 2., 5.
	Insurance Coverage (18)	<input type="checkbox"/> A6015 Insurance Coverage (not complex)	1., 2., 5., 8.
	Other Contract (37)	<input type="checkbox"/> A6009 Contractual Fraud <input type="checkbox"/> A6031 Tortious Interference <input type="checkbox"/> A6027 Other Contract Dispute(not breach/insurance/fraud/negligence)	1., 2., 3., 5. 1., 2., 3., 5. 1., 2., 3., 8.
	Eminent Domain/Inverse Condemnation (14)	<input type="checkbox"/> A7300 Eminent Domain/Condemnation Number of parcels _____	2.
	Wrongful Eviction (33)	<input type="checkbox"/> A6023 Wrongful Eviction Case	2., 6.
Real Property	Other Real Property (26)	<input type="checkbox"/> A6018 Mortgage Foreclosure <input type="checkbox"/> A6032 Quiet Title <input type="checkbox"/> A6060 Other Real Property (not eminent domain, landlord/tenant, foreclosure)	2., 6. 2., 6. 2., 6.
	Unlawful Detainer-Commercial (31)	<input type="checkbox"/> A6021 Unlawful Detainer-Commercial (not drugs or wrongful eviction)	2., 6.
Unlawful Detainer	Unlawful Detainer-Residential (32)	<input type="checkbox"/> A6020 Unlawful Detainer-Residential (not drugs or wrongful eviction)	2., 6.
	Unlawful Detainer- Post-Foreclosure (34)	<input type="checkbox"/> A6020F Unlawful Detainer-Post-Foreclosure	2., 6.
	Unlawful Detainer-Drugs (38)	<input type="checkbox"/> A6022 Unlawful Detainer-Drugs	2., 6.

SHORT TITLE: Corber, et al. v. McKesson, et al.

CASE NUMBER

	A Civil Case Cover Sheet Category No.	B Type of Action (Check only one)	C Applicable Reasons (See Steps Above)
Judicial Review	Asset Forfeiture (05)	<input type="checkbox"/> A6108 Asset Forfeiture Case	2., 6.
	Petition re Arbitration (11)	<input type="checkbox"/> A6115 Petition to Compel/Confirm/Vacate Arbitration	2., 5.
	Writ of Mandate (02)	<input type="checkbox"/> A6151 Writ - Administrative Mandamus <input type="checkbox"/> A6152 Writ - Mandamus on Limited Court Case Matter <input type="checkbox"/> A6153 Writ - Other Limited Court Case Review	2., 8. 2. 2.
	Other Judicial Review (39)	<input type="checkbox"/> A6150 Other Writ /Judicial Review	2., 8.
Provisionally Complex Litigation	Antitrust/Trade Regulation (03)	<input type="checkbox"/> A6003 Antitrust/Trade Regulation	1., 2., 8.
	Construction Defect (10)	<input type="checkbox"/> A6007 Construction Defect	1., 2., 3.
	Claims Involving Mass Tort (40)	<input checked="" type="checkbox"/> A6006 Claims Involving Mass Tort	1., 2., 8.
	Securities Litigation (28)	<input type="checkbox"/> A6035 Securities Litigation Case	1., 2., 8.
	Toxic Tort Environmental (30)	<input type="checkbox"/> A6036 Toxic Tort/Environmental	1., 2., 3., 8.
	Insurance Coverage Claims from Complex Case (41)	<input type="checkbox"/> A6014 Insurance Coverage/Subrogation (complex case only)	1., 2., 5., 8.
Enforcement of Judgment	Enforcement of Judgment (20)	<input type="checkbox"/> A6141 Sister State Judgment <input type="checkbox"/> A6160 Abstract of Judgment <input type="checkbox"/> A6107 Confession of Judgment (non-domestic relations) <input type="checkbox"/> A6140 Administrative Agency Award (not unpaid taxes) <input type="checkbox"/> A6114 Petition/Certificate for Entry of Judgment on Unpaid Tax <input type="checkbox"/> A6112 Other Enforcement of Judgment Case	2., 9. 2., 6. 2., 9. 2., 8. 2., 8. 2., 8., 9.
	RICO (27)	<input type="checkbox"/> A6033 Racketeering (RICO) Case	1., 2., 8.
Miscellaneous Civil Complaints	Other Complaints (Not Specified Above) (42)	<input type="checkbox"/> A6030 Declaratory Relief Only <input type="checkbox"/> A6040 Injunctive Relief Only (not domestic/harassment) <input type="checkbox"/> A6011 Other Commercial Complaint Case (non-tort/non-complex) <input type="checkbox"/> A6000 Other Civil Complaint (non-tort/non-complex)	1., 2., 8. 2., 8. 1., 2., 8. 1., 2., 8.
	Partnership Corporation Governance (21)	<input type="checkbox"/> A6113 Partnership and Corporate Governance Case	2., 8.
Miscellaneous Civil Petitions	Other Petitions (Not Specified Above) (43)	<input type="checkbox"/> A6121 Civil Harassment <input type="checkbox"/> A6123 Workplace Harassment <input type="checkbox"/> A6124 Elder/Dependent Adult Abuse Case <input type="checkbox"/> A6190 Election Contest <input type="checkbox"/> A6110 Petition for Change of Name <input type="checkbox"/> A6170 Petition for Relief from Late Claim Law <input type="checkbox"/> A6100 Other Civil Petition	2., 3., 9. 2., 3., 9. 2., 3., 9. 2. 2., 7. 2., 3., 4., 8. 2., 9.

SHORT TITLE: Corber, et al. v. McKesson, et al.	CASE NUMBER
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Item III. Statement of Location: Enter the address of the accident, party's residence or place of business, performance, or other circumstance indicated in Item II., Step 3 on Page 1, as the proper reason for filing in the court location you selected.

REASON: Check the appropriate boxes for the numbers shown under Column C for the type of action that you have selected for this case. <input type="checkbox"/> 1. <input checked="" type="checkbox"/> 2. <input checked="" type="checkbox"/> 3. <input type="checkbox"/> 4. <input type="checkbox"/> 5. <input type="checkbox"/> 6. <input type="checkbox"/> 7. <input type="checkbox"/> 8. <input type="checkbox"/> 9. <input type="checkbox"/> 10.		ADDRESS: Margallt Corber 5818 Lindley Ave. Encino, CA 91316
CITY:	STATE:	ZIP CODE:

Item IV. Declaration of Assignment: I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that the above-entitled matter is properly filed for assignment to the Stanley Mosk courthouse in the Central District of the Superior Court of California, County of Los Angeles [Code Civ. Proc., § 392 et seq., and Local Rule 2.0, subds. (b), (c) and (d)].

Dated: November 15, 2012


(SIGNATURE OF ATTORNEY/FILING PARTY)

PLEASE HAVE THE FOLLOWING ITEMS COMPLETED AND READY TO BE FILED IN ORDER TO PROPERLY COMMENCE YOUR NEW COURT CASE:

1. Original Complaint or Petition.
2. If filing a Complaint, a completed Summons form for issuance by the Clerk.
3. Civil Case Cover Sheet, Judicial Council form CM-010.
4. Civil Case Cover Sheet Addendum and Statement of Location form, LACIV 109, LASC Approved 03-04 (Rev. 03/11).
5. Payment in full of the filing fee, unless fees have been waived.
6. A signed order appointing the Guardian ad Litem, Judicial Council form CIV-010, if the plaintiff or petitioner is a minor under 18 years of age will be required by Court in order to issue a summons.
7. Additional copies of documents to be conformed by the Clerk. Copies of the cover sheet and this addendum must be served along with the summons and complaint, or other initiating pleading in the case.

EXHIBIT B

1 ELISE R. SANGUINETTI (CA SBN: 191389)
2 AMANDA J. GREENBURG (CA SBN: 255767)
3 KHORRAMI, LLP
4 360 22nd Street, Suite 640
5 Oakland, California 94612
6 Telephone: (510) 867-2000
7 Facsimile: (866) 546-7377
8 Email: ESanguinetti@khorrami.com

9 TREVOR B. ROCKSTAD (CA SBN: 277274)
10 DAVIS & CRUMP PC
11 1712 15th Street, Suite 300
12 Gulfport, MS 39501
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16 TARA TABATABAIE (OK Bar No. 21838)
17 THE SILL LAW GROUP PLLC
18 14005 N. Eastern Avenue
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24 PEARSON RANDALL & SCHUMACHER, PA
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26 Suite 1025
27 Minneapolis, MN 55402
28 612-767-7500
Fax: 612-767-7501
Email: srandall@prslegal.com
Attorneys for JCCP Petitioners

JUDICIAL COUNCIL OF CALIFORNIA

CHAIR OF THE JUDICIAL COUNCIL

RACHEL RENTZ, et al.,

Plaintiffs,

vs.

MCKESSON CORPORATION, et al.,

Defendants.

) LOS ANGELES SUPERIOR COURT
) CASE NO.: BC 483765

) PETITION FOR COORDINATION

) *[Filed concurrently with Declaration of*
) *Elise Sanguinetti; Memorandum of*
) *Points and Authorities ISO Petition for*
) *Coordination]*

1 TO THE HONORABLE TANI G. CANTIL-SAKAUYE, CHAIRPERSON OF THE
2 CALIFORNIA JUDICIAL COUNCIL, CHIEF JUSTICE OF CALIFORNIA:

3 Pursuant to the California Code of Civil Procedure Section 404, et seq., and
4 California Rules of Court 3.500, et seq., plaintiffs and petitioners *RACHEL RENTZ; GEORGLA*
5 *METCALFE; VIVIAN PONCE; JERRY HALL; CLAUDETTA MCCLAIN; ERIC CANTRELL*
6 through counsel, Khoirami, LLP, respectfully submit this request to the Chairperson of the
7 Judicial Council for assignment of a judge to determine whether the above-titled actions and
8 included joined actions are complex actions and, if so, whether coordination of the actions is
9 appropriate.

10 The petitioners and plaintiffs in the included actions all allege use of the prescription
11 medication containing the active ingredient propoxyphene sold under various generic and brand
12 names including Darvon and Darvocet and consequent injuries including, but not limited to,
13 heart arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial infarctions, and/or
14 sudden death.

15 This petition for coordination is based upon the criteria codified in *California Code of*
16 *Civil Procedure* § 404.1. That is, in the Darvocet cases sought to be coordinated herein:

17 One judge hearing all of the actions for all purposes in a selected site or sites will
18 promote the ends of justice taking into account whether common questions of fact or law
19 are predominating and significant to the litigation; the convenience of parties, witnesses,
20 and counsel; the relative development of the actions and the work product of counsel; the
21 efficient utilization of judicial facilities and manpower; the calendar of the courts; the
22 disadvantages of the duplicative and inconsistent rulings, orders or judgments; and, the
23 likelihood of settlement of the actions without further litigation should coordination be
24 denied. (*California Code of Civil Procedure* § 404.1).

25 All of the cases sought to be coordinated herein involve use of the pharmaceutical
26 medication containing the active ingredient propoxyphene and consequent injuries including, but
27 not limited to heart arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial
28 infarctions, and/or sudden death (hereinafter "Darvocet related injury cases"). Such cases are
more particularly described in the accompanying Declaration of Elise Sanguinetti, the
accompanying memorandum of points and authorities, exhibits attached thereto including

1 conformed copies of complaints filed in said actions, and other supporting documents submitted
2 herewith.

3 The actions sought to be coordinated fall within the definition of "complex litigation"
4 under Section 19 of the Standards of Judicial Administration and Rule 3.400 et seq., of the
5 California Rules of Court. (See the Declaration of Elise Sanguinetti filed herewith.) Petitioners
6 are currently seeking to coordinate theseven (7) actions listed below. However, Petitioners'
7 counsel is informed and believes that scores of additional propoxyphene related injury cases will
8 be filed within the next weeks. Petitioners will seek to join these additional cases via "Add-On
9 Petitions."

10 1. *Terry Freitas and Lori Freitas, husband and wife; Oleta Burney and Harold*
11 *Burney, wife and husband; Donald Green, individually and as husband and next of kin to Mary*
12 *Green, Deceased; Charles Hearn, a single man; John Jenkins, a single man, Linda Miller and*
13 *Anthony Miller, wife and husband; Barbara Reed, individually and as wife and next of kin to*
14 *Raymond Reed, deceased; Martha Poole, a single woman, vs. McKesson Corporation; Eli Lilly*
15 *& Company; AAI Pharma, Inc; AAI Pharma LLC; AAI Development Services, Inc.; Neosan*
16 *Pharmaceuticals Inc.; Xanodyne Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.;*
17 *Vintage Pharmaceuticals, Inc.; Propst Distribution, Inc.; Brenn Distribution, Inc.; Vintage*
18 *Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics*
19 *Bidco II, LLC; Generics International (US Parent), Inc.; Endo Pharmaceuticals, Inc.; Endo*
20 *Pharmaceuticals Holdings, Inc.; and DOES 1 thru 50, inclusive; filed in San Francisco County*
21 *Superior Court on 10/31/2011, Case No. CGC-11-515537;*

22 2. *Mary Keene and George Keene, wife and husband; Judy Humphrey, a single*
23 *woman; Marty Armstrong, a single man; Diane Bane, a single woman; Linda Brown, a single*
24 *woman; Doris Dowdy, a single woman; Darlene Hibler, a single woman; Tiffany Hughes, a*
25 *single woman; Imogene Mealer, a single woman; Jessie Miller, a single woman; Deidra Minor,*
26 *a single woman; Lettie Perkins, a single woman; William Sherrill and Becky Sherrill, husband*
27 *and wife; Brenda Shields, a single woman; Thomas Strzyz and Trixy Strzyz, husband and wife;*
28 *Linzo Taylor and Nadine Taylor, husband and wife; Sharon Waller, a single woman; Vanissa*

1 *White, a single woman; Mary Bearden, a single woman; Michael Brooks, a single man; Jerry*
 2 *Gibson and Katherine Gibson, husband and wife; Jackie Jackson, a single woman; Moseetta*
 3 *Wortham, a single woman; Virgie Hopper, individually and as daughter and next of kin to Lola*
 4 *Hopper, deceased; Avensky Clayborn, individually and as son and next of kin to Belinda*
 5 *Clayborn, deceased; Bobbie Osborn, individually and as daughter and next of kin to Joann*
 6 *Spears, deceased; vs. McKesson Corporation; Eli Lilly & Company; AAI Pharma, Inc; AAI*
 7 *Pharma LLC; AAI Development Services, Inc.; Neosan Pharmaceuticals Inc.; AAI Pharma*
 8 *Services, Inc.; Xanodyne Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage*
 9 *Pharmaceuticals, Inc.; Propst Distribution, Inc.; Brenn Distribution, Inc.; Brenn*
 10 *Manufacturing, Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.;*
 11 *Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Endo*
 12 *Pharmaceuticals, Inc.; Endo Pharmaceuticals Holdings, Inc.; Cornerstone Pharmaceuticals,*
 13 *Inc.; Cornerstone Biopharma, Inc.; Cornerstone Biopharma Holdings, Inc.; Teva*
 14 *Biopharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Mylan Pharmaceuticals, Inc.;*
 15 *Mylan, Inc.; Covidien PLC; Covidien Inc.; Mallinckrodt Inc.; Watson Pharmaceuticals, Inc.;*
 16 *and DOES 1 through 50, inclusive, filed in San Francisco County Superior on 11/18/2011, Case*
 17 *No. CGC-11-516031;*

18 3. *Tenessia Posey, Megan Stinson, Barbara J. Olson, Mary A. Alsop, Clifford*
 19 *August, Charlie Bell, Wrildia A. Blackburn, Dorothy Bonds, Terrence Brown, Delores*
 20 *Christopher, Dorothy A. Cowan, Christine W. Graham, Mary L. Gremillion, Martha R. Grooms,*
 21 *Margaret R. Harmon, Kay F. Jones, Anthony B. Kenner, Suzanne Manuel, John H. Moore, Paul*
 22 *M. Nelson, Carilee Pemberton, Kenneth J. Tambaugh, Sheila G. Sullivan, Casa Thomas vs.*
 23 *McKesson Corporation; Eli Lilly & Company; AAI Pharma, Inc; AAI Pharma LLC; AAI*
 24 *Development Services, Inc.; Neosan Pharmaceuticals Inc.; AAI Pharma Services, Inc.;*
 25 *Xanodyne Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage Pharmaceuticals,*
 26 *Inc.; Propst Distribution, Inc.; Brenn Distribution, Inc.; Brenn Manufacturing, Inc.; Vintage*
 27 *Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics*
 28 *Bidco II, LLC; Generics International (US Parent), Inc; Endo Pharmaceuticals, Inc.; Endo*

1 *Pharmaceuticals Holdings Inc.; Cornerstone Pharmaceuticals, Inc.; Cornerstone Biopharma,*
 2 *Inc.; Cornerstone Biopharma Holdings, Inc.; Teva Biopharmaceuticals, Inc.; Teva*
 3 *Pharmaceuticals USA, Inc.; Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Covidien PLC; Covidien*
 4 *Inc.; Mallinckrodt Inc.; Watson Pharmaceuticals, Inc.; and DOES 1 through 50, inclusive, filed*
 5 *in San Francisco County Superior Court on 11/18/2011, Case No. CGC-11-515995;*

6 4. *Wendell Rice and Patricia Rice, husband and wife; Roy Bell and Laurel Bell,*
 7 *husband and wife; Linda Mahorney and David Mahorney, wife and husband; Jay Mason and*
 8 *Sharon Mason, husband and wife; William Barker and Ann Barker, husband and wife; Teddy*
 9 *Teasley And Joyce Teasley, husband and wife; Ilmaid Khalil and Roxanne Khalil, husband and*
 10 *wife; Beverly Rodriguez, a single woman; Mary Dries and Andrew Dries, wife and husband;*
 11 *Joseph Roy, a single man; Wanda Thomas and Bernard Thomas, wife and husband; Harry*
 12 *Stepp, a single man; Mitchell Ashley and Geraldine Ashley, husband and wife; Ethel Newberry,*
 13 *a single woman; Mary Price-Thomas, a single woman; and Fannie Smith, a single woman, vs.*
 14 *McKesson Corporation; Eli Lilly & Company; AAI Pharma, Inc; AAI Pharma LLC; AAI*
 15 *Development Services, Inc; Neosan Pharmaceuticals Inc.; AAI Pharma Services, Inc.; Xanodyne*
 16 *Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage Pharmaceuticals, Inc.; Propst*
 17 *Distribution, Inc.; Brenn Distribution, Inc.; Brenn Manufacturing, Inc.; Vintage*
 18 *Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics*
 19 *Bidco II, LLC; Generics International (US Parent), Inc.; Endo Pharmaceuticals, Inc.; Endo*
 20 *Pharmaceuticals Holdings Inc.; Cornerstone Pharmaceuticals, Inc.; Cornerstone Biopharma,*
 21 *Inc.; Cornerstone Biopharma Holdings, Inc.; Teva Biopharmaceuticals, Inc.; Teva*
 22 *Pharmaceuticals USA, Inc.; Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Covidien PLC; Covidien*
 23 *Inc.; Mallinckrodt Inc.; Watson Pharmaceuticals, Inc.; and DOES 1 through 100, inclusive,*
 24 *filed in San Francisco County Superior Court on 11/15/2011, Case No. CGC-11-515897;*

25 5. *Harry D. Witthauer, a married man; Marina Damas, a married individual; Joyce*
 26 *Auston, a married woman; Minnie Beasley, a married woman; Teresa Hash, a single individual;*
 27 *Gary Hatfield, a married man; Billy Hoskins, a married man; Kenneth Delavergnie, Jr., a*
 28 *married man; Edith Langlois, a single woman; Donna Quesinberry, a single woman; Kay*

1 *Romero, a single woman; Donna Romero, a single woman; Diane Saucier, a married woman;*
 2 *Joyce Brown, a married woman; Gary Tackett, a married man; Ronald T. Miller, a married*
 3 *man; Kim Ragan, a married woman; Helen Timmons, a single woman; Beverly Webb, a single*
 4 *woman; Charles T. Hibbard, a married man; Frances Ziegler, a single man; Jeffie Mills, a*
 5 *single individual; Jennifer Walker nka Jennifer Dunn and Janet Dunn, individually and as*
 6 *daughters and next of kin to Drexel Dunn, deceased; Edward Murray, individually and as*
 7 *husband and next of kin to Margaret Murray, deceased; Willam O'Banion and Leesa O'Banion,*
 8 *individually and as son and daughter-in-law, respectively and as next of kin to Jackinell*
 9 *O'Banion, deceased; Avis Ortego, individually and as son and next of kin to Margaret Ortego,*
 10 *deceased; Patricia Jackson, individually and as mother and next of kin to Priscilla Pile,*
 11 *deceased; Sarah Hinson, individually and as daughter and next of kin to Dorothy Smith,*
 12 *deceased; and Thurman Stacy, individually and as husband and next of kin to Shelby Stacy,*
 13 *deceased, vs. McKesson Corporation; Eli Lilly & Company; AAI Pharma, Inc.; AAI Pharma*
 14 *LLC; AAI Development Services, Inc.; Neosan Pharmaceuticals Inc.; AAI Pharma Services,*
 15 *Inc.; Xanodyne Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage*
 16 *Pharmaceuticals, Inc.; Propst Distribution, Inc.; Brenn Distribution, Inc.; Brenn*
 17 *Manufacturing, Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.;*
 18 *Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Endo*
 19 *Pharmaceuticals, Inc.; Endo Pharmaceuticals Holdings Inc.; Cornerstone Pharmaceuticals,*
 20 *Inc.; Cornerstone Biopharma, Inc.; Cornerstone Biopharma Holdings, Inc.; Teva*
 21 *Biopharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Ivax Pharmaceuticals, Inc.; Mylan*
 22 *Pharmaceuticals, Inc.; Mylan, Inc.; Covidien PLC; Covidien, Inc.; Mallinckrodt Inc.; Watson*
 23 *Pharmaceuticals, Inc.; and DOES I through 100, inclusive, filed in San Francisco County*
 24 *Superior Court on 11/18/2011, Case No. CGC-11-515994.*

25 6. *Lawrence B. Fields Robinson, by and through his Guardian ad Litem,*
 26 *Diane Laws; Joseph Lee Laverine Fields, by and through his Guardian ad Litem, Diane Laws,*
 27 *vs. Eli Lilly and Company; Watson Pharmaceuticals, Inc. and DOES 1-100 inclusive, filed in*
 28 *Los Angeles County Superior Court on 12/16/2011, Case No. KC 062737.*

7. Rachel Rentz; Georgia Metcalfe; Vivian Ponce; Jerry Hall; Claudetta McClain; Eric Cantrell Vs. McKesson Corporation; Eli Lilly And Company; Xanodyne Pharmaceuticals, Inc.; Teva Biopharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage Pharmaceuticals, Inc.; Propst Distribution, Inc.; Brenn Distribution, Inc.; Brenn Manufacturing, Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Endo Pharmaceuticals, Inc.; Endo Pharmaceuticals Holdings Inc.; Cornerstone Pharmaceuticals, Inc.; Cornerstone Biopharma, Inc.; Cornerstone Biopharma Holdings, Inc.; And Does 1 thru 50, inclusive, filed in Los Angeles County Superior Court on 5/3/2012, Case No. BC483765.

Proof of filing of a Notice of Submission of Petition for Coordination and a copy of this Petition in each included action will be submitted to the Chair of the Judicial Council pursuant to Rule 3.522 of the California Rules of Court. Proof of filing of any further documents to be submitted pursuant to Rule 3.523 of the California Rules of Court will be submitted to the Chair of the Judicial Council within the time frames provided by Rules 3.522 and 3.523.

This Petition is based upon the accompanying Memorandum of Points and Authorities, and the Declaration of Elise Sanguinetti filed herewith and the exhibits attached thereto.

A hearing on this petition for coordination is requested.

DATED: Oct. 23, 2012

Respectfully submitted,

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JUDICIAL COUNCIL OF CALIFORNIA

CHAIR OF THE JUDICIAL COUNCIL

23	RACHEL RENTZ, et al.,)	LOS ANGELES COUNTY SUPERIOR
24)	COURT CASE NO.: BC 483765
24	Plaintiffs,)	MEMORANDUM OF POINTS AND
25	vs.)	AUTHORITIES IN SUPPORT OF
25)	PETITION FOR COORDINATION
26	MCKESSON CORPORATION, et al.,)	
27)	<i>[Filed concurrently with Petition for</i>
27	Defendants.)	<i>Coordination; Declaration of Elise</i>
28)	<i>Sanguinetti]</i>

I. INTRODUCTION

Petitioner is aware of a total of seven (7) cases that have been filed in California Superior Courts on behalf of persons that have developed, among other injuries, cardiac injuries and/or sudden death (hereinafter "Darvocet related injuries") from ingesting Darvocet and other prescription medication containing the active ingredient propoxyphene (hereinafter the "Darvocet Product"). All of the actions at issue name the same group of defendants: the distributor, MCKESSON CORPORATION; the brand name manufacturer, ELI LILLY AND COMPANY; the generic manufacturers¹ of the Darvocet Product.; and DOES 1 through 50, inclusive. Petitioners' counsel plans to file additional similar cases in California Superior Courts within the next several weeks. Further, counsel is informed that, aside from the additional cases that we will file shortly, scores of similar cases will be filed soon involving consumption of the Darvocet Product and consequent diagnosis of Darvocet related injuries.

Plaintiffs/petitioners seek coordination of the following seven (7) actions that are known to be filed in the State of California and involve the same defective Darvocet Product, the same or substantially similar causes of action, the same or substantially similar issues of law, the same or substantially similar issue of material fact:

1. *Terry Freitas and Lori Freitas, husband and wife; Oleta Burney and Harold Burney, wife and husband; Donald Green, individually and as husband and next of kin to Mary Green, Deceased; Charles Hearn, a single man; John Jenkins, a single man, Linda Miller and Anthony Miller, wife and husband; Barbara Reed, individually and as wife and next of kin to Raymond Reed, deceased; Martha Poole, a single woman, vs. Mckesson Corporation; Eli Lilly & Company; AAI*

¹ AAI PHARMA, INC; AAI PHARMA LLC; AAI DEVELOPMENT SERVICES, INC.; NEOSAN PHARMACEUTICALS INC.; AAI PHARMA SERVICES, INC.; XANODYNE PHARMACEUTICALS, INC.; QUALITEST PHARMACEUTICALS, INC.; VINTAGE PHARMACEUTICALS, INC.; PROPST DISTRIBUTION, INC.; BRENN DISTRIBUTION, INC.; BRENN MANUFACTURING, INC.; VINTAGE PHARMACEUTICALS, LLC; GENERICS INTERNATIONAL (US), INC.; GENERICS BIDCO I, LLC; GENERICS BIDCO II, LLC; GENERICS INTERNATIONAL (US PARENT), INC.; ENDO PHARMACEUTICALS, INC.; ENDO PHARMACEUTICALS HOLDINGS INC.; CORNERSTONE PHARMACEUTICALS, INC.; CORNERSTONE BIOPHARMA, INC.; CORNERSTONE BIOPHARMA HOLDINGS, INC.; TEVA BIOPHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; IVAX PHARMACEUTICALS, INC.; MYLAN PHARMACEUTICALS, INC.; MYLAN, INC.; COVIDIEN PLC; COVIDIEN, INC.; MALLINCKRODT INC.; WATSON PHARMACEUTICALS, INC.

Pharma, Inc.; AAI Pharma LLC; AAI Development Services, Inc.; Neosan Pharmaceuticals Inc.;
 Xanodyne Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage Pharmaceuticals, Inc.;
 Propst Distribution, Inc.; Brenn Distribution, Inc.; Vintage Pharmaceuticals, LLC; Generics
 International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US
 Parent), Inc.; Endo Pharmaceuticals, Inc.; Endo Pharmaceuticals Holdings, Inc.; and DOES 1 thru
 50, inclusive; filed in San Francisco County Superior Court on 10/31/2011, Case No. CGC-11-
 515537;

2. Mary Keene and George Keene, wife and husband; Judy Humphrey, a single woman;
 Marty Armstrong, a single man; Diane Bane, a single woman; Linda Brown, a single woman; Doris
 Dowdy, a single woman; Darlene Hibler, a single woman; Tiffany Hughes, a single woman; Imogene
 Mealer, a single woman; Jessie Miller, a single woman; Deidra Minor, a single woman; Lettie
 Perkins, a single woman; Martha Poole, a single woman; William Sherrill and Becky Sherrill,
 husband and wife; Brenda Shields, a single woman; Thomas Strzyz and Trixy Strzyz, husband and
 wife; Linzo Taylor and Nadine Taylor, husband and wife; Sharon Waller, a single woman; Vanissa
 White, a single woman; Mary Bearden, a single woman; Michael Brooks, a single man; Jerry Gibson
 and Katherine Gibson, husband and wife; Jackie Jackson, a single woman; Moseetta Wortham, a
 single woman; Virgie Hopper, individually and as daughter and next of kin to Lola Hopper,
 deceased; Avenky Clayborn, individually and as son and next of kin to Belinda Clayborn, deceased;
 Bobbie Osborn, individually and as daughter and next of kin to Joann Spears, deceased; vs.
 McKesson Corporation; Eli Lilly & Company; AAI Pharma, Inc.; AAI Pharma LLC; AAI
 Development Services, Inc.; Neosan Pharmaceuticals Inc.; AAI Pharma Services, Inc.; Xanodyne
 Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage Pharmaceuticals, Inc.; Propst
 Distribution, Inc.; Brenn Distribution, Inc.; Brenn Manufacturing, Inc.; Vintage Pharmaceuticals,
 LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics
 International (US Parent), Inc.; Endo Pharmaceuticals, Inc.; Endo Pharmaceuticals Holdings, Inc.;
 Cornerstone Pharmaceuticals, Inc.; Cornerstone Biopharma, Inc.; Cornerstone Biopharma
 Holdings, Inc.; Teva Biopharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Mylan
 Pharmaceuticals, Inc.; Mylan, Inc.; Covidien PLC; Covidien Inc.; Mallinckrodt Inc.; Watson

1 *Pharmaceuticals, Inc.; and DOES 1 through 50, inclusive, filed in San Francisco County Superior on*
 2 *11/18/2011, Case No. CGC-11-516031;*

3 3. *Tenessia Posey, Megan Stinson, Barbara J. Olson, Mary A. Alsop, Clifford August,*
 4 *Charlie Bell, Wrildia A. Blackburn, Dorothy Bonds, Terrence Brown, Delores Christopher, Dorothy*
 5 *A. Cowan, Christine W. Graham, Mary L. Gremillion, Martha R. Grooms, Margaret R. Harmon, Kay*
 6 *F. Jones, Anthony B. Kenner, Suzanne Manuel, John H. Moore, Paul M. Nelson, Carilee Pemberton,*
 7 *Kenneth J. Tambaugh, Sheila G. Sullivan, Casa Thomas vs. McKesson Corporation; Eli Lilly &*
 8 *Company; AAI Pharma, Inc; AAI Pharma LLC; AAI Development Services, Inc.; Neosan*
 9 *Pharmaceuticals Inc.; AAI Pharma Services, Inc.; Xanodyne Pharmaceuticals, Inc.; Qualitest*
 10 *Pharmaceuticals, Inc.; Vintage Pharmaceuticals, Inc.; Propst Distribution, Inc.; Brenn Distribution,*
 11 *Inc.; Brenn Manufacturing, Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.;*
 12 *Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc; Endo*
 13 *Pharmaceuticals, Inc.; Endo Pharmaceuticals Holdings Inc.; Cornerstone Pharmaceuticals, Inc.;*
 14 *Cornerstone Biopharma, Inc.; Cornerstone Biopharma Holdings, Inc.; Teva Biopharmaceuticals,*
 15 *Inc.; Teva Pharmaceuticals USA, Inc.; Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Covidien PLC;*
 16 *Covidien Inc.; Mallinckrodt Inc.; Watson Pharmaceuticals, Inc.; and DOES 1 through 50, inclusive,*
 17 *filed in San Francisco County Superior Court on 11/18/2011, Case No. CGC-11-515995;*

18 4. *Wendell Rice and Patricia Rice, husband and wife; Roy Bell and Laurel Bell, husband*
 19 *and wife; Linda Mahorney and David Mahorney, wife and husband; Jay Mason and Sharon Mason,*
 20 *husband and wife; William Barker and Ann Barker, husband and wife; Teddy Teasley And Joyce*
 21 *Teasley, husband and wife; Ilmaid Khalil and Roxanne Khalil, husband and wife; Beverly Rodriguez,*
 22 *a single woman; Mary Dries and Andrew Dries, wife and husband; Joseph Roy, a single man;*
 23 *Wanda Thomas and Bernard Thomas, wife and husband; Harry Stepp, a single man; Mitchell Ashley*
 24 *and Geraldine Ashley, husband and wife; Ethel Newberry, a single woman; Mary Price-Thomas, a*
 25 *single woman; and Fannie Smith, a single woman, vs. McKesson Corporation; Eli Lilly & Company;*
 26 *AAI Pharma, Inc; AAI Pharma LLC; AAI Development Services, Inc; Neosan Pharmaceuticals Inc.;*
 27 *AAI Pharma Services, Inc.; Xanodyne Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.;*
 28 *Vintage Pharmaceuticals, Inc.; Propst Distribution, Inc.; Brenn Distribution, Inc.; Brenn*

1 *Manufacturing, Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.; Generics*
 2 *Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Endo*
 3 *Pharmaceuticals, Inc.; Endo Pharmaceuticals Holdings Inc.; Cornerstone Pharmaceuticals, Inc.;*
 4 *Cornerstone Biopharma, Inc.; Cornerstone Biopharma Holdings, Inc.; Teva Biopharmaceuticals,*
 5 *Inc.; Teva Pharmaceuticals USA, Inc.; Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Covidien PLC;*
 6 *Covidien Inc.; Mallinckrodt Inc.; Watson Pharmaceuticals, Inc.; and DOES I through 100, inclusive,*
 7 *filed in San Francisco County Superior Court on 11/15/2011, Case No. CGC-11-515897;*

8 5. *Harry D. Witthauer, a married man; Marina Damas, a married individual; Joyce*
 9 *Auston, a married woman; Minnie Beasley, a married woman; Teresa Hash, a single individual;*
 10 *Gary Hatfield, a married man; Billy Hoskins, a married man; Kenneth Delavergnie, Jr., a married*
 11 *man; Edith Langlois, a single woman; Donna Quesinberry, a single woman; Kay Romero, a single*
 12 *woman; Donna Romero, a single woman; Diane Saucier, a married woman; Joyce Brown, a*
 13 *married woman; Gary Tackett, a married man; Ronald T. Miller, a married man; Kim Ragan, a*
 14 *married woman; Helen Timmons, a single woman; Beverly Webb, a single woman; Charles T.*
 15 *Hibbard, a married man; Frances Ziegler, a single man; Jeffie Mills, a single individual; Jennifer*
 16 *Walker nka Jennifer Dunn and Janet Dunn, individually and as daughters and next of kin to Drexel*
 17 *Dunn, deceased; Edward Murray, individually and as husband and next of kin to Margaret Murray,*
 18 *deceased; Willam O'Banion and Leesa O'Banion, individually and as son and daughter-in-law,*
 19 *respectively and as next of kin to Jackinell O'Banion, deceased; Avis Ortego, individually and as son*
 20 *and next of kin to Margaret Ortego, deceased; Patricia Jackson, individually and as mother and next*
 21 *of kin to Priscilla Pile, deceased; Sarah Hinson, individually and as daughter and next of kin to*
 22 *Dorothy Smith, deceased; and Thurman Stacy, individually and as husband and next of kin to Shelby*
 23 *Stacy, deceased, vs. McKesson Corporation; Eli Lilly & Company; AAI Pharma, Inc.; AAI Pharma*
 24 *LLC; AAI Development Services, Inc.; Neosan Pharmaceuticals Inc.; AAI Pharma Services, Inc.;*
 25 *Xanodyne Pharmaceuticals, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage Pharmaceuticals, Inc.;*
 26 *Propst Distribution, Inc.; Brenn Distribution, Inc.; Brenn Manufacturing, Inc.; Vintage*
 27 *Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II,*
 28 *LLC; Generics International (US Parent), Inc.; Endo Pharmaceuticals, Inc.; Endo Pharmaceuticals*

1 *Holdings Inc.; Cornerstone Pharmaceuticals, Inc.; Cornerstone Biopharma, Inc.; Cornerstone*
 2 *Biopharma Holdings, Inc.; Teva Biopharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Ivax*
 3 *Pharmaceuticals, Inc.; Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Covidien PLC; Covidien, Inc.;*
 4 *Mallinckrodt Inc.; Watson Pharmaceuticals, Inc.; and DOES I through 100, inclusive, filed in San*
 5 *Francisco County Superior Court on 11/18/2011, Case No. CGC-11-515994.*

6 6. *Lawrence B. Fields Robinson, by and through his Guardian ad Litem, Diane Laws;*
 7 *Joseph Lee Laverine Fields, by and through his Guardian ad Litem, Diane Laws, vs. Eli Lilly and*
 8 *Company; Watson Pharmaceuticals, Inc. and DOES 1-100 inclusive, filed in Los Angeles County*
 9 *Superior Court on 12/16/2011, Case No. KC 062737.*

10 7. *Rachel Rentz; Georgia Metcalfe; Vivian Ponce; Jerry Hall; Claudetta McClain; Eric*
 11 *Cantrell Vs. McKesson Corporation; Eli Lilly And Company; Xanodyne Pharmaceuticals, Inc.; Teva*
 12 *Biopharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Qualitest Pharmaceuticals, Inc.; Vintage*
 13 *Pharmaceuticals, Inc.; Propst Distribution, Inc.; Brenn Distribution, Inc.; Brenn Manufacturing,*
 14 *Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC;*
 15 *Generics Bidco II, LLC; Generics International (US Parent), Inc.; Endo Pharmaceuticals, Inc.; Endo*
 16 *Pharmaceuticals Holdings Inc.; Cornerstone Pharmaceuticals, Inc.; Cornerstone Biopharma,*
 17 *Inc.; Cornerstone Biopharma Holdings, Inc.; And Does 1 thru 50, inclusive, filed in Los Angeles*
 18 *County Superior Court on 5/3/2012, Case No. BC483765.*

19 In all seven matters, Plaintiffs allege, among other injuries, cardiac injuries and/or sudden
 20 death along with loss of consortium claims caused by use of Darvocet/Propoxyphene. Accordingly,
 21 while each plaintiff's medical background and special damages may be unique, each case shares the
 22 same general liability facts and issues against the defendants, the same scientific facts and issues
 23 concerning the Darvocet Product and consequent injuries, and the same or similar treatment protocols
 24 for the Darvocet related injuries. Petitioners' counsel anticipates that the actions will, therefore,
 25 involve duplicative requests for the same defendant witness depositions and the same documents
 26 related to development, manufacturing, testing, marketing, and sale of the Darvocet Product. Absent
 27 coordination of these actions by a single judge, there is a significant likelihood of duplicative
 28 discovery, waste of judicial resources and possible inconsistent judicial rulings on legal issues.

1 Plaintiffs and petitioners submit that Los Angeles County is the most appropriate choice as a
 2 coordination venue for the Darvocet Product cases. Los Angeles County has a complex litigation
 3 panel at the Central Civil West Division and said panel has extensive experience in handling
 4 coordinated actions similar to the cases at issue in this Petition. These actions constitute complex
 5 litigation under Section 19 of the Standards of Judicial Administration and Rule 3.400., et seq., of the
 6 California Rules of Court, thus, coordination and assignment to a complex panel is appropriate. The
 7 cases were not originally filed as complex cases. However, pursuant to California Rule of Court (c)
 8 (5), the cases are complex as they are claim involving mass tort. (See Declaration of Elise
 9 Sanguinetti ¶ 6.)

10 Plaintiffs and petitioners respectfully request that the Judicial Council appoint a coordination
 11 motion judge. Petitioners further submit that the interests of justice and judicial economy support the
 12 coordination of the seven (7) Darvocet Product cases as well as other such cases that may be filed
 13 before this Petition is decided. Finally, petitioners urge the Judicial Council to designate Los Angeles
 14 County Central Civil West Division as the coordination venue.

15 II.

16 ARGUMENT

17 A. THE DARVOCET CASES AGAINST DEFENDANTS ARE APPROPRIATE 18 CASES FOR COORDINATION PURSUANT TO CODE OF CIVIL 19 PROCEDURE SECTION 404.1

20 Pursuant to *California Code of Civil Procedure* § 404, the petitioners currently seek
 21 coordination of seven (7) actions involving more than 100 personal injury claimants that used
 22 Darvocet and thereafter suffered injury and/or death and additional 20 plaintiffs that have suffered
 23 resulting loss of consortium as a result. These seven (7) actions are pending in San Francisco
 24 County Superior Court and Los Angeles County Superior Court against the same group of
 25 defendants. Use of committees and standardized discovery in a coordinated setting will expedite
 26 resolution of these cases, avoid inconsistent results, and assist in alleviating onerous burdens on the
 27 courts as well as the parties.
 28

1 The factors set forth in *California Code of Civil Procedure* § 404.1 must be weighed in
 2 determining whether coordination under *California Code of Civil Procedure* § 404, in selecting the
 3 site or sites for the coordinated proceedings and the coordination trial judge under Section 404.3, and
 4 in selecting the reviewing court under Section 404.3. The following factors, catalogued in section
 5 404.1 and discussed in more detail below, all demonstrate that coordination of these included actions
 6 is appropriate: One judge hearing all of the actions for all purposes in a selected site or sites will
 7 promote the ends of justice; Common questions of fact or law are predominating and significant to
 8 the litigation; Coordination may serve the convenience of parties, witnesses, and counsel the relative
 9 development of the actions and the work product of counsel; Coordination may facilitate the efficient
 10 utilization of judicial facilities and manpower; Coordination may enhance the orderly calendar of the
 11 courts; Without coordination, the parties may suffer from disadvantages caused by duplicative and
 12 inconsistent rulings, orders or judgments; and, without coordination, settlement of the actions without
 13 further litigation is unlikely.

14 1. COMMON QUESTIONS OF FACT OR LAW ARE PREDOMINATING
 15 AND SIGNIFICANT

16 These included actions are more similar than dissimilar. The actions share substantially the
 17 same defendants, the same acts and omissions, the same product and the same general medical
 18 consequences caused by the product. Each action alleges the same general claims, including theories
 19 of liability, causation and damages as allegedly caused by the Darvocet Product (See Exhibit 1 to
 20 Declaration of Elise Sanguinetti).

21 The facts relied on to show that each included action meets the coordination standards
 22 specific in CCP Section 404.1 are those as alleged in the complaints – specifically, those facts alleged
 23 in the general factual allegation sections of the complaints. The general allegations in each of these
 24 complaints state that the plaintiffs suffered, among other injuries, cardiac injury and/or sudden death
 25 following exposure to the product and that the defendants failed to warn patients and physicians
 26 regarding all known and knowable risks associated with the product.

27 The actions involve common questions of law that predominate and are significant to the
 28 litigation. These common questions of law and fact include, but are not limited to:

- 1 1. Whether there are design and/or manufacturing defects in the defendants' Darvocet
- 2 Product;
- 3 2. Whether the defendants failed to adequately warn physicians and consumers regarding
- 4 all known and knowable risks associated with the Darvocet Product;
- 5 3. Whether the defendants' conduct in designing, manufacturing, and marketing the
- 6 Darvocet Product fell below the applicable duties of care owed by the defendants to the plaintiffs;
- 7 4. Whether the defendants intentionally, deliberately, knowingly, carelessly, recklessly,
- 8 or negligently misrepresented, omitted, concealed or suppressed material and important information
- 9 regarding the true and known risks of the product from the plaintiffs and their physicians;
- 10 5. Whether the defendants' misconduct constitutes negligence;
- 11 6. Whether the defendants' conduct constitutes negligence;
- 12 7. Whether the plaintiffs are entitled to compensatory damages and/or restitution, and if
- 13 so, the method by which such relief should be determined; and
- 14 8. Whether the defendants are liable for punitive or exemplary damages, a matter to be
- 15 determined when appropriate, and if so, the amount necessary and appropriate to punish them for
- 16 their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary
- 17 damages.

18 Thus, the similarities of the parties and the issues of liability and scientific causation justify
19 coordination of these actions.

20 2. **THE RELATIVE DEVELOPMENT OF THE ACTIONS AND THE**
21 **WORK PRODUCT OF COUNSEL WEIGH IN FAVOR OF**
22 **COORDINATION PROCEEDINGS**

23 *California Code of Civil Procedure* § 404.1 suggests that the Judicial Council and the
24 coordination motion judge weigh the "relative development of the actions and the work product of
25 counsel" in determining whether coordination is appropriate. However, in all cases sought to be
26 coordinated, the complaints have only recently been filed. In all of the cases, no responsive
27 pleadings have yet been filed. Therefore, this factor does not preclude coordination of these actions
28 at this time, as coordination will not penalize any particular individual case.

1 Additionally, in light of the similarity of the actions, there will be duplicate discovery
 2 obligations upon the common defendants unless coordination is ordered. Coordination before
 3 initiation of discovery in any of the cases will eliminate waste of resources and will facilitate
 4 economy. Thus, this factor weighs in favor of prompt coordination.

5 **3. COORDINATION WOULD FOSTER EFFICIENT UTILIZATION OF**
 6 **JUDICIAL RESOURCES**

7 At present, these actions are pending in San Francisco County and Los Angeles County.
 8 More actions will likely be filed in other counties across this State. No one can seriously dispute that
 9 coordination would foster judicial consistencies and result in efficient use of the court's resources as
 10 well as the parties' resources. Conversely, unless coordinated, these cases would likely be assigned
 11 to different judges in different counties, thereby undermining judicial economy.

12 **4. DUPLICATIVE AND INCONSISTENT RULINGS AND ORDERS**
 13 **WILL LIKELY OCCUR IF MULTIPLE COURTS ARE ADDRESSING**
 14 **THE SAME ISSUES**

15 Failure to coordinate these actions will result in the disadvantages of duplicate and
 16 inconsistent rulings, orders, or judgments. The inevitability of realizing the inconsistency and
 17 duplication factor of California Code of Civil Procedure Section 404.1, weighs heavily in favor of
 18 coordination. Indeed, issues likely to be raised in this action include issues pertaining to liability,
 19 allocation of fault and contribution, as well as the same wrongful conduct of defendants. Such
 20 difficult issues may ultimately be addressed by the California Court of Appeal. Coordination is
 21 required in order to avoid duplicative efforts and inconsistent rulings.

22 **5. IF COORDINATION IS DENIED, IT IS NOT LIKELY THAT THESE**
 23 **CASES WILL SETTLE WITHOUT FURTHER LITIGATION**

24 The final factor to be considered under California Code of Civil Procedure 404.1 is "the
 25 likelihood of settlement of the actions without further litigation should coordination be denied." It is
 26 highly unlikely that denial of coordination would foster settlement. The included actions are in
 27 litigation on multiple claims and significant issues. With multi-millions of dollars at stake, these
 28 cases are sure to be seriously litigated. Generally, coordination assists in the settlement process

1 because the parties, at the Court's urging, are forced to create organized plans for mediation or
 2 settlement. If experience is a guide, coordination will not only lead to greater efficiencies in the
 3 litigation process, it will also lead to coordinated settlement discussions.

4 **B. A STAY OF ALL DARVON CASES PENDING IN CALIFORNIA STATE**
 5 **COURTS IS NECESSARY AND WARRANTED TO EFFECT THE PURPOSES OF**
 6 **COORDINATION**

7 The ends of justice will be well-served by ordering a stay of the pending Darvon actions. A
 8 brief stay pending determination of coordination will ensure the uniformity, consistency and
 9 predictability of pre-trial discovery and other proceedings.

10 Currently, there is outstanding case activity which requires a stay in various cases. All the
 11 cases have upcoming court requirements such as motion work and Case Management Conferences.

12 Petitioning Plaintiff will be requesting an order staying the California Darvon cases pending
 13 resolution of the Petition for Coordination. This limited stay will prevent the wasteful expenditure of
 14 resources to individual case motions while coordination is considered. Additionally, a stay will
 15 prevent inconsistent rulings and a waste of judicial resources pending a decisions by the assigned
 16 judge on the Petition for Coordination.

17 **III.**

18 **CONCLUSION**

19 As set forth above, all factors to be considered demonstrate that coordination of these
 20 included actions is appropriate as it is in the interest of judicial economy and the parties.

21 DATED: Oct. 23, 2012

22 Respectfully submitted,

23 By Elise R. Sanguinetti
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 25 AMANDA J. GREENBURG (CA SBN: 255767)
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Attorneys for Plaintiffs

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
 IN AND FOR THE COUNTY OF SAN FRANCISCO

TERRY FREITAS, et al., Plaintiffs, vs. MCKESSON CORPORATION, et al., Defendants.) CASE NO.: CGC-11-515537)) MEMORANDUM OF POINTS AND) AUTHORITIES IN SUPPORT OF) PLAINTIFFS' MOTION TO STAY) PROCEEDINGS PENDING) RESOLUTION OF PLAINTIFFS') PETITION FOR COORDINATION)) DATE: December 6, 2012) TIME: 9:00am 9:13 am.) DEPT: 302
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Plaintiffs submit this Memorandum of Points and Authorities in Support of their Motion to Stay Proceedings Pending Resolution of Plaintiffs' Petition For Coordination. Plaintiffs have brought the exact same motion in all Darvon cases filed in San Francisco.

I. STATEMENT OF FACTS

This lawsuit concerns personal injuries related to Plaintiffs' ingestion of prescription medication containing the active ingredient Propoxyphene for treatment of mild to moderate pain.

1 The Propoxyphene medication was marketed and sold as generic and/or brand-name drugs under
 2 various names including Darvon and Darvocet. In addition to the Plaintiffs bringing this lawsuit,
 3 there are additional cases before this Court and cases filed in Los Angeles Superior Court making
 4 similar allegations regarding personal injuries related to prescription medications containing the
 5 active ingredient Propoxyphene.

6 In the Propoxyphene cases before the Court, Defendants have brought numerous motions.
 7 The following Motions are currently pending before this Court:

8 1. *Terry Freitas and Lori Freitas, etc., et al., vs. McKesson Corporation, et al.* CGC-11-
 9 515537:

- 10 a. Motion to Dismiss for Forum Non Conveniens brought by multiple by Vintage
- 11 Pharmaceuticals, LLC et al., and joined by multiple Defendants.
- 12 b. Demurrer on Ground of Improper Joinder brought by Vintage Pharmaceuticals,
- 13 LLC and joined by multiple Defendants.
- 14 c. Motion to Quash Service of Summons brought by Xanodyne Pharmaceuticals, Inc.

15 2. *Mary Keene and George Keene, et al., vs. McKesson Corporation, et al.* CGC-11-
 16 510631:

- 17 a. Motion to Quash Service of Summons brought by Xanodyne Pharmaceuticals, Inc.
- 18 b. Motion to Dismiss for Forum Non Conveniens brought by Teva Pharmaceuticals
- 19 USA, Inc..
- 20 c. Motion to Sever Based on Improper Joinder brought by Teva Pharmaceuticals
- 21 USA, Inc..

22 3. *Tenessia Posey, et al., vs. McKesson Corporation, et al.* CGC-11-515995:

- 23 a. Motion to Dismiss for Forum Non Conveniens brought by multiple by Xanodyne
- 24 Pharmaceuticals, Inc. and joined by multiple Defendants.
- 25 b. Demurrer on Ground of Improper Joinder brought by Xanodyne Pharmaceuticals,
- 26 Inc. and joined by multiple Defendants.
- 27 c. Motion to Quash Service of Summons brought by Xanodyne Pharmaceuticals, Inc.

1 4. *Wendell Rice and Patricia Rice, et al., vs. McKesson Corporation et al.* CGC-11-
2 515897:

3 a. Motion to Dismiss for Forum Non Conveniens brought by multiple by Xanodyne
4 Pharmaceuticals, Inc. and joined by multiple Defendants.

5 b. Demurrer on Ground of Improper Joinder brought by Xanodyne Pharmaceuticals,
6 Inc. and joined by multiple Defendants.

7 c. Motion to Quash Service of Summons brought by Xanodyne Pharmaceuticals, Inc.

8 5. *Harry D. Witthauer, et al., vs. McKesson Corporation et al.* CGC-11-515994:

9 a. Motion to Dismiss for Forum Non Conveniens brought by multiple by Xanodyne
10 Pharmaceuticals, Inc. and joined by multiple Defendants.

11 b. Demurrer on Ground of Improper Joinder brought by Xanodyne Pharmaceuticals,
12 Inc. and joined by multiple defendants.

13 c. Motion to Quash Service of Summons brought by Xanodyne Pharmaceuticals, Inc.

14 In addition to these five cases filed in San Francisco Superior Court, there are two additional
15 cases filed in Los Angeles Superior Court that concern injuries related to Propoxyphene ingestion.
16 The additional cases are *Lawrence B. Fields Robinson, etc. et al., vs. Eli Lilly and Company, et al.*,
17 KC062737 and *Rachel Rentz et al., vs. McKesson Corporation et al.*, BC483765. Further, it is
18 expected that additional cases related to Propoxyphene ingestion will be filed in California Courts in
19 the near future.

20 These motions were scheduled to be heard on November 6, 2012 and November 8, 2012.
21 This Court allowed the motion date to be pushed back until December 18, 2012 to allow the Judicial
22 Council time to review the coordination. As of today's date, a decision has not been made by the
23 Judicial Council. Also, Plaintiffs' will be filing an Application for Stay Order before the Judicial
24 Council.

25 On October 23, 2012, the Plaintiffs in the above referenced cases filed a Petition for
26 Coordination to consolidate these cases pursuant to *California Code of Civil Procedure § 404, et seq.*
27 and California Rules of Court 3.500, *et seq.* In order to avoid the possibility of conflicting rulings,
28

1 avoid prejudice to the parties and promote judicial efficiency, Plaintiffs now ask this Court to stay
 2 ruling on and hearing the motions in these various Propoxyphene cases pending a decision on
 3 coordination from the Judicial Council.

4 II. ARGUMENT

5 A. A Stay Should Be Granted Pending a Decision on the Plaintiffs' Motion for 6 Coordination.

7 This Court has the authority to grant Plaintiffs' request to stay the current proceedings
 8 pending a decision on coordination of the California Propoxyphene cases, as "[t]rial courts generally
 9 have the inherent power to stay proceedings in the interests of justice and to promote judicial
 10 efficiency." *Freiberg v. City of Mission Viejo*, 33 Cal. App. 4th 1484, 1489 (1995).

11 California Code of Civil Procedure § 187 gives this Court discretion to "adopt any suitable
 12 process or mode of proceeding . . . which may appear most comfortable to the spirit of this code."
 13 *Cal. Civ. Proc. Code* §187. This Court's authority to stay proceedings is part of its "inherent power"
 14 to "insure the orderly administration of justice". *Bailey v. Fosca Oil Co. Ltd.*, (1963) 216 Cal. App. 2d
 15 813,817-818 (approving of trial court's stay pursuant to Cal. Civ. Code § 187). Moreover, the
 16 California Rules of Court Rule 3.515(a) allows courts to stay proceedings in any action being
 17 considered for coordination. Specifically, Rule 3.515 provides:

18 (a) Any party may file a motion for an order under Code of Civil
 19 Procedure section 404.5 staying the proceedings in any action being
 20 considered for, or affecting an action being considered for, coordination,
 or the court may stay the proceedings on its own motion.

21 As noted earlier, this action involves plaintiffs who suffered heart related injuries as the result
 22 of using various name brand and generic Propoxyphene containing medications. It involves factual
 23 allegations and claims for relief that are similar to numerous other cases that have been filed in
 24 California. Coordination of all the California Propoxyphene cases makes sense. All the cases
 25 involve the same defective medication, allege the same or substantially similar causes of action,
 26 involve the same or substantially similar issues of law, and involve the same or substantially similar
 27 issues of material fact. As of October 23, 2012, Plaintiffs have filed a Petition for Coordination of the
 28

1 cases in this action. An analysis of all factors to be considered regarding consolidation set out in
2 California Code of Civil Procedure § 400 *et seq.* weighs in favor of consolidation. (See Declaration
3 of Elise Sanguinetti indicating that the petition has been filed and can be produced to this Court upon
4 request.) Thus, it is very likely that these cases will indeed proceed to coordination.

5 In multiple cases, Defendants have filed multiple Demurrers on the ground of Improper
6 Joinder, multiple Motions to Dismiss for Forum Non Conveniens and multiple Motions to Quash
7 Service. All of these motions concern issues that should be brought before the coordination judge
8 and uniformly decided at one time so as to avoid inconsistent rulings and promote the interests of
9 justice. If the Judicial Council orders coordination, the transferee court will address the same issues
10 as this Court if the case is not stayed.

11 If this Court proceeds with the pending Motions, the Court will have to continue to expend
12 time and resources on issues that may ultimately be addressed in another forum after coordination.

13 III. CONCLUSION

14 For the foregoing reasons, the Plaintiffs' Motion To Stay Proceedings Pending Resolution of
15 Plaintiffs' Pending Petition for Coordination should be GRANTED.

16 DATED: November 9, 2012

KHORRAMI, LLP

17
18 By: 
19 ELISE R. SANGUINETTI
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20 Attorneys for JCCP Petitioners

21 JUDICIAL COUNCIL OF CALIFORNIA

22 CHAIR OF THE JUDICIAL COUNCIL

23 RACHEL RENTZ, et al.,

24 Plaintiffs,

25 vs.

26 MCKESSON CORPORATION, et al.,

27 Defendants.

) LOS ANGELES COUNTY SUPERIOR
) COURT CASE NO.: BC 483765
)
) **DECLARATION OF ELISE**
) **SANGUINETTI IN SUPPORT OF**
) **PETITION FOR COORDINATION**
) *[Filed concurrently with Petition for*
) *Coordination; Points and Authorities in*
) *Support of Petition for Coordination]*

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I, Elise Sanguinetti, declare and state as follows:

1. I am an attorney at law duly licensed to practice law in all courts of the State of California and am a managing attorney at Khorrami LLP. I have personal knowledge of the matters set forth herein, and if called upon to testify, would be competent to do so under oath.

2. This petition is brought for the purpose of seeking coordination of seven (7) complaints, which involve claims of numerous injured plaintiffs, alleging use of the prescription medication containing the active ingredient Propoxyphene sold under various generic and brand names including Darvon and Darvocet (hereinafter the "Product") and plaintiffs' consequent injuries including, but not limited to, cardiac injuries and/or sudden death. Each complaint asserts causes of action arising from common claims and allegations against the defendants and each involves identical issues of law.

3. The names of the parties to all known pending product cases in California state courts and the names and address of each party's attorney of record, along with the complete title of each included action are listed in Exhibit 1 attached hereto. The petitioners seek to coordinate all actions included in Exhibit 1.

4. All of the cases allege generally similar theories of liability, including strict liability, negligence, breach of implied and express warranties, and violations of Business and Professions Code 17200 and 17500 arising from defendants' manufacture and distribution of the Product.

5. At present, no other action is known to be pending in a court of this state that shares common questions of fact or law with the included actions.

6. The subject cases are complex pursuant to California Rule of Court 3.400(b) and (c). Not only are these cases a mass tort, they will include the following: (1) Numerous pretrial motions raising difficult or novel legal issues that will be time-consuming to resolve; (2) Management of a large number of witnesses or a substantial amount of documentary evidence; and (3) Coordination with related actions pending in one or more courts in other counties, states or countries, or in federal court. The subject cases arise out of injuries sustained by plaintiffs due to their exposure to the Product; therefore, the cases will include complex scientific and medical issues which consistently

1 trigger numerous pre-trial motions. The subject cases assert claims against large pharmaceutical
2 companies and will, therefore, necessarily involve several corporate witnesses, scientific researchers,
3 advertising and marketing consultants as well as multiple treating physicians for each plaintiff. In
4 addition, cases involving manufacture, marketing and sale of a prescription drug often result in the
5 production of large amounts of documentary evidence. The cases were not originally filed as complex
6 cases. However, pursuant to California Rule of Court (c) (5), the cases are complex as they are claim
7 involving mass tort.

8 7. The actions sought to be coordinated meet the standards described in California Code
9 of Civil Procedure section 404.1. The actions involve common questions of law and fact that
10 predominate and are significant to the litigation. These common questions of law and fact include,
11 but are not limited to:

- 12 a) whether there are design and/or manufacturing defects in the defendants'
13 Product;
- 14 b) Whether the defendants failed to adequately warn physicians and consumers
15 regarding all known and knowable risks associated with the Product and/or
16 whether warnings were vitiated by defendants' advertising and marketing
17 campaigns;
- 18 c) Whether the defendants' conduct in designing, manufacturing, and marketing
19 of the Product fell below the applicable duties of care owed by the defendants
20 to the plaintiffs;
- 21 d) Whether the defendants intentionally, deliberately, knowingly, carelessly,
22 recklessly, or negligently misrepresented, omitted, concealed or suppressed
23 material and important information regarding the true and known risks of the
24 Product from the plaintiffs and their physicians;
- 25 e) Whether the defendants' misconduct constitutes breaches of any warranties
26 recognized by law;
- 27 f) Whether the defendants' conduct constitutes negligence;

- g) Whether the plaintiffs are entitled to compensatory damages and/or restitution, and if so, the method by which such relief should be determined; and
- h) Whether the defendants are liable for punitive or exemplary damages, a matter to be determined when appropriate and if so, the amount necessary and appropriate to punish them for their conduct, to deter, and to fulfill the other policies and purposes of punitive damages.

8. Coordination of these related actions will serve the convenience of the parties, witnesses and counsel because discovery in these overlapping actions is likely to be duplicative if they proceed separately. Coordination of these actions will prevent repetitive and redundant depositions regarding the same issues by witnesses. In addition, without coordination, duplicative motions concerning the adequacy of the pleadings, the admissibility of scientific evidence and other matters are sure to arise.

9. All cases (except the Rentz case) were filed in October and November of 2011. Shortly after filing, Defendant Eli Lilly & Company removed all five cases to federal court where they were quickly transferred and made part of In re: Darvocet, Darvon and Propoxyphene Products Liability Litigation, MDL No. 2226, before the Honorable Danny C. Reeves in the United States District Court for the Eastern District of Kentucky. Once in the MDL, counsel for plaintiffs and petitioners fought to have their respective cases remanded back to California State Court. As such, the coordination of these actions will not severely disrupt the progress of any individual action. Below is a timeline of this activity:

Case Name/No.	Date Filed in California Superior Court	Removal by Defendants to USDC, NDCA	Remand Motions Filed by Plfs	Remand Granted by MDL Judge, re-remanding case back to CASup. Court
<i>Freitas, et al.</i> , CGC-11-515537	10/31/2011	12/6/2011	1/4/2012 in NDCA; re-filed on 2/27/2012 in MDL	7/2/2012
<i>Keene, et al.</i> , CGC-11-516031	11/18/2011	1/24/2012	7/4/2012	7/31/2012
<i>Rice, et al.</i> , CGC-11-515897	11/15/2011	1/24/2012	7/13/2012	8/7/2012

1	<i>Posey, et al.</i> , CGC-11-515995	11/18/2011	1/24/2012	7/14/2012	8/7/2012
2	<i>Witthauer, et al.</i> , CGC-11-515994	11/18/2011	1/24/2012	7/14/2012	8/7/2012
3	<i>LBFR et al.</i> , KC062737	12/16/2011	1/30/2012	5/18/2012	7/16/2012
4	<i>Rentz et al.</i> BC 483765	5/3/20012	N/A	N/A	N/A

10. Absent coordination, redundant duplicative discovery and motion practice in these overlapping actions would waste litigant and judicial resources. Duplicative discovery will result in unnecessary copying costs, expert costs, depositions costs and filing fees. In addition, the need to take the same depositions in each of these actions will likely increase travel costs for all the litigants' counsel.

11. Failure to coordinate these actions creates a risk of inconsistent or duplicative judgments and orders. Without coordination, two or more separate courts will decide essentially the same issues and may render different rulings on liability and other issues. Coordination of these actions in a single court would avoid this possibility.

12. Absent coordination, settlement of the individual actions is unlikely. Generally, the primary motivating factors for settling cases are the elimination of further litigation, the avoidance of the risk of an adverse judgment at trial and the avoidance of additional litigation costs. If the cases are not coordinated, the incentive to settle any of these cases is drastically reduced. Settlement of one of these cases may not end the litigation in the other two cases, leaving defendants with a continued risk of adverse judgment and substantial litigation costs. Only if the defendants are able to settle these claims in a coordinated action is there any realistic possibility of settlement.

8. Attached as Exhibit 2 is a true and correct copy of the complaint, *Terry Freitas and Lori Freitas, husband and wife, et al., vs. McKesson Corporation; Eli Lilly & Company; et al.*, Case No. CGC-11-515537, filed on 10/31/2011 (San Francisco County Superior Court);

9. Attached as Exhibit 3 is a true and correct copy of the complaint, *Mary Keene and George Keene, wife and husband, et al., vs. McKesson Corporation; Eli Lilly & Company; et al.*, Case No. CGC-11-516031, filed on 11/18/2011 (San Francisco County Superior Court);

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge George King and the assigned discovery Magistrate Judge is Ralph Zarefsky.

The case number on all documents filed with the Court should read as follows:

CV12- 9986 GHK (RZx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

=====

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

☒ **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

☐ **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

☐ **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEETI (a) PLAINTIFFS (Check box if you are representing yourself ☐)MARGALIT CORBER, RENE CARO, STEVE DANTZLER,
LINDA SOWARDS, LORI HUISMAN, ET AL.

DEFENDANTS

see attachment

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)
see attachmentAttorneys (If Known)
see attachment

II. BASIS OF JURISDICTION (Place an X in one box only.)

- ☐ 1 U.S. Government Plaintiff ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant.)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in this State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. ORIGIN (Place an X in one box only.)

- ☐ 1 Original Proceeding ☒ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check 'Yes' only if demanded in complaint.)CLASS ACTION under F.R.C.P. 23: ☐ Yes ☒ No☐ MONEY DEMANDED IN COMPLAINT: \$

VI. CAUSE OF ACTION (Cite the U. S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

§ 28 U.S.C. §§ 1332, 1441, 1446, AND 1453; Removal of Product Liability Action based on Class Action Fairness Act and Federal Question

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES	CONTRACT	TORTS PERSONAL INJURY	TORTS PERSONAL PROPERTY	PRISONER PETITIONS	LABOR
<input type="checkbox"/> 400 State Reapportionment	<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 370 Other Fraud	<input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus	<input type="checkbox"/> 710 Fair Labor Standards Act
<input type="checkbox"/> 410 Antitrust	<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 315 Airplane Product Liability	<input type="checkbox"/> 371 Truth in Lending	<input type="checkbox"/> 530 General	<input type="checkbox"/> 720 Labor/Mgmt. Relations
<input type="checkbox"/> 430 Banks and Banking	<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 380 Other Personal Property Damage	<input type="checkbox"/> 535 Death Penalty	<input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act
<input type="checkbox"/> 450 Commerce/ICC Rates/etc.	<input type="checkbox"/> 140 Negotiable Instrument	<input type="checkbox"/> 330 Fed. Employers' Liability	<input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 540 Mandamus/Other	<input type="checkbox"/> 740 Railway Labor Act
<input type="checkbox"/> 460 Deportation	<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 340 Marine	BANKRUPTCY	<input type="checkbox"/> 550 Civil Rights	<input type="checkbox"/> 790 Other Labor Litigation
<input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations	<input type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 22 Appeal 28 USC 158	<input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 791 Empl. Ret. Inc. Security Act
<input type="checkbox"/> 480 Consumer Credit	<input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Veterans)	<input type="checkbox"/> 350 Motor Vehicle	<input type="checkbox"/> 423 Withdrawal 28 USC 157	FORFEITURE / PENALTY	PROPERTY RIGHTS
<input type="checkbox"/> 490 Cable/Sat TV	<input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits	<input type="checkbox"/> 355 Motor Vehicle Product Liability	CIVIL RIGHTS	<input type="checkbox"/> 610 Agriculture	<input type="checkbox"/> 820 Copyrights
<input type="checkbox"/> 810 Selective Service	<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 441 Voting	<input type="checkbox"/> 620 Other Food & Drug	<input type="checkbox"/> 830 Patent
<input type="checkbox"/> 850 Securities/Commodities/Exchange	<input type="checkbox"/> 190 Other Contract	<input type="checkbox"/> 362 Personal Injury-Med Malpractice	<input type="checkbox"/> 442 Employment	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881	<input type="checkbox"/> 840 Trademark
<input type="checkbox"/> 875 Customer Challenge 12 USC 3410	<input type="checkbox"/> 195 Contract Product Liability	<input checked="" type="checkbox"/> 365 Personal Injury-Product Liability	<input type="checkbox"/> 443 Housing/Accommodations	<input type="checkbox"/> 630 Liquor Laws	SOCIAL SECURITY
<input type="checkbox"/> 890 Other Statutory Actions	<input type="checkbox"/> 196 Franchise	<input type="checkbox"/> 368 Asbestos Personal Injury Product Liability	<input type="checkbox"/> 444 Welfare	<input type="checkbox"/> 640 R.R. & Truck	<input type="checkbox"/> 61 HIA(1395ff)
<input type="checkbox"/> 891 Agricultural Act	REAL PROPERTY	<input type="checkbox"/> 462 Naturalization Application	<input type="checkbox"/> 445 American with Disabilities - Employment	<input type="checkbox"/> 650 Airline Regs	<input type="checkbox"/> 862 Black Lung (923)
<input type="checkbox"/> 892 Economic Stabilization Act	<input type="checkbox"/> 210 Land Condemnation	IMMIGRATION	<input type="checkbox"/> 446 American with Disabilities - Other	<input type="checkbox"/> 660 Occupational Safety /Health	<input type="checkbox"/> 863 DIWC/DIWW 405(g))
<input type="checkbox"/> 893 Environmental Matters	<input type="checkbox"/> 220 Foreclosure	<input type="checkbox"/> 463 Habeas Corpus-Alien Detainee	<input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 690 Other	<input type="checkbox"/> 864 SSID Title XVI
<input type="checkbox"/> 894 Energy Allocation Act	<input type="checkbox"/> 230 Rent Lease & Ejectment	<input type="checkbox"/> 465 Other Immigration Actions			<input type="checkbox"/> 865 RSI (405(g))
<input type="checkbox"/> 895 Freedom of Info. Act	<input type="checkbox"/> 240 Torts to Land				FEDERAL TAX SUITS
<input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice	<input type="checkbox"/> 245 Tort Product Liability				<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)
<input type="checkbox"/> 950 Constitutionality of State Statutes	<input type="checkbox"/> 290 All Other Real Property				<input type="checkbox"/> 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: **CV 12 9986**

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☒ No ☐ Yes

If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☐ No ☒ Yes

If yes, list case number(s): 12-cv-04399-PSG(Ex); 12-cv-00818-JFW(PLAx); 11-cv-06147-PSG(Ex); 12-cv-04399-PSG(Ex)

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)

- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☒ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH named plaintiff resides.

☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH named defendant resides.

☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	San Francisco County, Alabama, Delaware, Indiana, Kentucky, Maryland, Nevada, North Carolina, Pennsylvania

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH claim arose.

Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Plaintiffs allege a substantial part of the events giving rise to this claim occurred within the County of Los Angeles	

* Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties

Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER):

Christopher Norton

Date November 20, 2012

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3 -1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

Attachment to Civil Cover Sheet CV-71

Item I.(a) — Defendants

MCKESSON CORPORATION; ELI LILLY AND COMPANY; AAIRPHARMA, INC.; AAIPHARMA LLC; AAI DEVELOPMENT SERVICES, INC.; NEOSAN PHARMACEUTICALS INC; XANODYNE PHARMACEUTICALS, INC.; QUALITEST PHARMACEUTICALS, INC.; VINTAGE PHARMACEUTICALS, INC.; PROBST DISTRIBUTION, INC.; BRENN DISTRIBUTION, INC.; BRENN MANUFACTURING, INC.; VINTAGE PHARMACEUTICALS, LLC; GENERICS INTERNATIONAL (US), INC.; GENERICS BIDCO I, LLC; GENERICS BIDCO II, LLC; GENERICS INTERNATIONAL (US PARENT), INC.; ENDO PHARMACEUTICALS, INC.; ENDO PHARMACEUTICALS HOLDINGS INC.; CONRERSTONE BIOPHARMA, INC.; CORNERSTONE BIOPHARMA HOLDINGS, INC.; TEVA BIOPHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; MYLAN PHARMACEUTICALS, INC.; MYLAN, INC.; COVIDIEN PLC; COVIDIEN INC.; MALLINCKRODT INC.; WATSON PHARMACEUTICALS, INC.; ABLE LABORATORIES; ARISTOS PHARMACEUTICALS, INC.; and DOES 1 through 50, inclusive,

Item I.(b) — Attorneys

Attorneys for Plaintiffs

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<p>Stephen D. Behnke, Esq. Wright & Schulte, LLC 812 E. National Raod Dayton, OH 45377 Tele: (937)435-7500 Fax: (937)435-7511</p>	

Attorneys for Defendants

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<p>Janet H. Kwuon REED SMITH LLP 355 South Grand Avenue, Suite 2900 Los Angeles, CA 90071 Tel: 213.457.8000; Fax: 213.457.8080 jkwuon@reedsmith.com Attorneys for Defendant Eli Lilly and Company</p>	<p>Adam R. Salvas Kenneth M. Seeger 455 Market Street, Suite 1530 San Francisco, CA 94105 Tel: 415.981.9260; Fax: 415.981.9266 asalvas@seegersalvas.com kseeger@seegersalvas.com Attorneys for Defendants Vintage Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Endo Pharmaceuticals Inc.; and Endo Pharmaceuticals Holdings Inc.</p>
<p>Carolyn Taylor Tammara N. Tukloff MORRIS POLICH & PURDY, LLP 600 W. Broadway, Suite 500 San Diego, CA 92101 Tel: 619.557-0404; Fax: 619.557.0460 Attorneys for Defendants Brenn Distribution, Inc. f/k/a Propst Distribution, Inc. f/k/a Qualitest Pharmaceuticals, Inc.; and Brenn Manufacturing, Inc. f/k/a Vintage Pharmaceuticals, Inc.</p>	<p>Karen Woodward Christopher P. Norton SEDGWICK LLP 801 S. Figueroa Street, 19th Floor Los Angeles, California 90017-5556 karen.woodward@sedgwicklaw.com christopher.norton@sedgwicklaw.com Tel: 213.426.6900; Fax: 213.426.6921 Attorneys for Defendant Xanodyne Pharmaceuticals, Inc.</p>
<p>Ginger Pigott Amy B. Alderfer GREENBERG TRAUIG, LLP 1840 Century Park East, Suite 1900 Los Angeles, CA 90067 Tel: (310) 586-7700; Fax: (310) 586- 7800 Attorneys for Defendant Teva Pharmaceuticals USA, Inc.</p>	